


MEDICAL POLICY	Cardiac: Implantable Loop Recorders (Medicare Only)
Effective Date: 9/1/2022	Medical Policy Number: 343
 9/1/2022	Medical Policy Committee Approved Date: 8/2022
Medical Officer	Date

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

Medicare Only

MEDICARE POLICY CRITERIA

The following Centers for Medicare & Medicaid Service (CMS) guidelines should be utilized for medical necessity coverage determinations. Click the link provided in the table below to access applicable medical necessity criteria. All listed guidelines apply.

Service	Medicare Guidelines
<i>Implantable Loop Recorders (ILR) or Implantable Cardiac Loop Recorders (ICLR) – Initial Placement and Replacement</i>	Company medical policy for Cardiac: Implantable Loop Recorder (All Lines of Business Except Medicare) I. This service may be considered medically necessary when the Company medical policy criteria are met. II. This service is considered not medically necessary for Medicare Plan members either when the Company medical policy criteria are not met <u>or</u> when a service is deemed “investigational” by the Company policy. <u>Services deemed “investigational” are considered not medically necessary for Medicare Plan members. See Policy Guidelines below.</u>

POLICY GUIDELINES

Medicare and Medical Necessity

National Coverage Determination (NCD) for Electrocardiographic Services (20.15) does mention implantable loop recorder (ILR) devices; however, the NCD does not provide coverage criteria specific to ILRs. The NCD states these devices are “implanted subcutaneously in a patient’s upper left chest and may remain implanted for many months. An ILR is used when syncope is thought to be cardiac-related, but is too infrequent to be detected by either a Holter™ monitor or a traditional pre-symptom MLR.”

The NCD also states, “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 MAC discretion.” The local MAC – Noridian – does not have an available local coverage determination (LCD) or article (LCA) with coverage criteria.

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. In the absence of Medicare coverage policies (e.g., manual, national coverage determination [NCD], local coverage determination [LCD], article [LCA], etc.), Medicare regulatory guidelines do allow Medicare Advantage Organizations (MAOs) to make their own coverage determinations, as long as the MAO applies an objective, evidence-based process, based on authoritative evidence. (*Medicare Managed Care Manual, Ch. 4, §90.5*)

Following an evidence-based assessment of current peer-reviewed medical literature, the Company may consider certain medical services or technologies to be “investigational.” The term “investigational” is not limited to devices or technologies which have not received the appropriate governmental regulatory approval (e.g., U.S. Food and Drug Administration [FDA]), but rather may also mean the procedure, device, or technology does not meet all of the Company’s technology assessment criteria, as detailed within the Company policy for *Definition: Experimental/Investigational* (MP5).

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)*. Thus, services which lack scientific evidence regarding safety and efficacy because they are investigational are “not medically reasonable or necessary” for Medicare Plan members. (*Medicare Claims Processing Manual, Ch. 23, §30 A*)

CPT/HCPCS CODES

Medicare Only	
Prior Authorization Required	
33285	Insertion, subcutaneous cardiac rhythm monitor, including programming
C1764	Event recorder, cardiac (implantable)

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E0616	Implantable cardiac event recorder with memory, activator and programmer
No Prior Authorization Required	
Note: Inclusion of a code in this section does not guarantee reimbursement or coverage. The following codes do not require routine review for medical necessity, but they may be subject to audit or benefit denial.	
33286	Removal, subcutaneous cardiac rhythm monitor
93285	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; subcutaneous cardiac rhythm monitor system
93290	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
93291	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; subcutaneous cardiac rhythm monitor system, including heart rhythm derived data analysis
93297	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
93298	Interrogation device evaluation(s), (remote) up to 30 days; subcutaneous cardiac rhythm monitor system, including analysis of recorded heart rhythm data, analysis, review(s) and report(s) by a physician or other qualified health care professional
G2066	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
0650T	Programming device evaluation (remote) of subcutaneous cardiac rhythm monitor system, with iterative adjustment of the implantable device to test the function of the device and select optimal permanently programmed values with analysis, review and report by a physician or other qualified health care professional

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

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.

MEDICAL POLICY CROSS REFERENCES

Cardiac: External Ambulatory Electrocardiography (Medicare Only), MP157

REFERENCES

1. Medicare Physician Fee Schedule (PFS) Relative Value Files; Available at:
<https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files>