

Leadless Pacemakers (NCD 20.8.4)

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[↪ Terms and Conditions](#)

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<p>Related Medicare Advantage Policy Guidelines</p> <ul style="list-style-type: none"> • Category III CPT Codes • Routine Costs in Clinical Trials (NCD 310.1)
<p>Related Medicare Advantage Coverage Summaries</p> <ul style="list-style-type: none"> • Cardiac Procedures: Pacemakers, Defibrillators and Pulmonary Artery Pressure Measurements • Experimental Procedures and Items, Investigational Devices and Clinical Trials

Policy Summary

[↪ See Purpose](#)

Overview

The leadless pacemaker eliminates the need for a device pocket and insertion of a pacing lead which are integral elements of traditional pacing systems. The removal of these elements eliminate an important source of complications associated with traditional pacing systems while providing similar benefits. Leadless pacemakers are delivered via catheter to the heart, and function similarly to other transvenous single-chamber ventricular pacemakers.

Guidelines

The Centers for Medicare & Medicaid Services (CMS) covers leadless pacemakers through Coverage with Evidence Development (CED). CMS covers leadless pacemakers when procedures are performed in Food and Drug Administration (FDA) approved studies. CMS also covers, in prospective longitudinal studies, leadless pacemakers that are used in accordance with the FDA approved label for devices that have either:

- An associated ongoing FDA approved post-approval study; or
- Completed an FDA post-approval study.

Each study must be approved by CMS and as a fully-described, written part of its protocol, must address the following research questions:

- What are the peri-procedural and post-procedural complications of leadless pacemakers?
- What are the long term outcomes of leadless pacemakers?
- What are the effects of patient characteristics (age, gender, comorbidities) on the use and health effects of leadless pacemakers?

CMS will review studies to determine if they meet the 13 criteria listed below. If CMS determines that they meet these criteria, the study will be posted on CMS' CED website (<https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html>).

- The principal purpose of the study is to test whether the item or service meaningfully improves health outcomes of affected beneficiaries who are represented by the enrolled subjects.
- The rationale for the study is well supported by available scientific and medical evidence.
- The study results are not anticipated to unjustifiably duplicate existing knowledge.

- d. The study design is methodologically appropriate and the anticipated number of enrolled subjects is sufficient to answer the research question(s) being asked in the National Coverage Determination.
- e. The study is sponsored by an organization or individual capable of completing it successfully.
- f. The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found in the Code of Federal Regulations (CFR) at 45 CFR Part 46. If a study is regulated by the Food and Drug Administration (FDA), it is also in compliance with 21 CFR Parts 50 and 56. In addition, to further enhance the protection of human subjects in studies conducted under CED, the study must provide and obtain meaningful informed consent from patients regarding the risks associated with the study items and/or services, and the use and eventual disposition of the collected data.
- g. All aspects of the study are conducted according to appropriate standards of scientific integrity.
- h. The study has a written protocol that clearly demonstrates adherence to the standards listed here as Medicare requirements.
- i. The study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Such studies may meet this requirement only if the disease or condition being studied is life threatening as defined in 21 CFR §312.81(a) and the patient has no other viable treatment options.
- j. The clinical research studies and registries are registered on the www.ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject. Registries are also registered in the Agency for Healthcare Research and Quality (AHRQ) Registry of Patient Registries (RoPR).
- k. The research study protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 12 months of the study's primary completion date, which is the date the final subject had final data collection for the primary endpoint, even if the trial does not achieve its primary aim. The results must include number started/completed, summary results for primary and secondary outcome measures, statistical analyses, and adverse events. Final results must be reported in a publicly accessible manner; either in a peer-reviewed scientific journal (in print or on-line), in an on-line publicly accessible registry dedicated to the dissemination of clinical trial information such as ClinicalTrials.gov, or in journals willing to publish in abbreviated format (e.g., for studies with negative or incomplete results).
- l. The study protocol must explicitly discuss beneficiary subpopulations affected by the item or service under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations in the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.
- m. The study protocol explicitly discusses how the results are or are not expected to be generalizable to affected beneficiary subpopulations. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with section 1142 of the Act, the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

All clinical research study protocols must be reviewed and approved by CMS. The principal investigator must submit the complete study protocol, identify the relevant CMS research question(s) that will be addressed and cite the location of the detailed analysis plan for those questions in the protocol, plus provide a statement addressing how the study satisfies each of the standards of scientific integrity (a. through m. listed above), as well as the investigator's contact information. The information will be reviewed, and approved studies will be identified on the CMS website.

Nationally Non-Covered Indications

Leadless pacemakers are non-covered when furnished outside of a CMS approved CED study.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws

that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
33274	Transcatheter insertion or replacement of permanent leadless pacemaker, right ventricular, including imaging guidance (e.g., fluoroscopy, venous ultrasound, ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed
33275	Transcatheter removal of permanent leadless pacemaker, right ventricular

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Modifier	Description
Q0	Investigational clinical service provided in a clinical research study that is in an approved clinical research study

Place of Service Code	Description
06	Indian Health Service Provider Based Facility
21	Inpatient Hospital
22	On Campus-Outpatient Hospital
26	Military Treatment Facility

Diagnosis Code	Description
Z00.6	Encounter for examination for normal comparison and control in clinical research program

References

CMS National Coverage Determinations (NCDs)

[Leadless Pacemakers \(20.8.4\)](#)

CMS Claims Processing Manual

[Chapter 32: § 380 Leadless Pacemakers](#)

CMS Transmittal(s)

[Transmittal 2955, Change Request 8401, Dated 05/14/2014 \(Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims\)](#)

MLN Matters

[Article MM8401, Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims](#)

UnitedHealthcare Commercial Policy

[Omnibus Codes](#)

Other(s)

[Medicare Managed Care Manual Chapter 4: § 10.7 Clinical Trials, CMS Website](#)

Guideline History/Revision Information

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

Date	Summary of Changes
04/01/2021	Template Update <ul style="list-style-type: none">Reformatted policy; transferred content to new template
08/12/2020	Applicable Codes <ul style="list-style-type: none">Removed CPT codes 0387T, 0388T, 0389T, 0390T, and 0391T Supporting Information <ul style="list-style-type: none">Updated <i>References</i> section to reflect the most current informationArchived previous policy version MPG367.04

Purpose

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers' submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as NCDs, LCDs, LCAs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the [References](#) section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

Terms and Conditions

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

Medicare Advantage Policy Guidelines are the property of UnitedHealthcare. Unauthorized copying, use, and distribution of this information are strictly prohibited.

*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the [Administrative Guide](#).