

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 201	Date: July 28, 2017
	Change Request 10117

SUBJECT: National Coverage Determination (NCD20.8.4): Leadless Pacemakers

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to inform contractors that effective January 18, 2017, CMS covers leadless pacemakers through Coverage with Evidence Development (CED) when procedures are performed in CMS-approved CED studies.

This revision to the Medicare National Coverage Determinations Manual is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, contractors with the Federal government that review and/or adjudicate claims, determinations, and/or decisions, quality improvement organizations, qualified independent contractors, the Medicare appeals council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

EFFECTIVE DATE: January 18, 2017

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: August 29, 2017 - for MAC local edits; January 2, 2018 - for MCS shared edits

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/Table of Contents
N	1/20.8.4/Leadless Pacemakers

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

**Business Requirements
Manual Instruction**

Attachment - Business Requirements

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IMPLEMENTATION DATE: August 29, 2017 - for MAC local edits; January 2, 2018 - for MCS shared edits

I. GENERAL INFORMATION

A. Background: 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 eliminates 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. Prior to January 18, 2017, there was no national coverage determination (NCD) in effect.

B. Policy: Effective January 18, 2017, 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.

All clinical research study protocols must address pre-specified research questions, adhere to standards of scientific integrity, and be reviewed and approved by CMS. Approved studies will be posted to the CMS website at <https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html>. Leadless pacemakers are non-covered outside of CMS approved studies.

The process for submitting a clinical research study to Medicare is outlined in the NCD Manual, Publication (Pub) 100-03, section 20.8.4. Associated claims processing instructions can be found at chapter 32, section 380, of Pub. 100-04, Claims Processing Manual.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC		H H H	M A C	D M E	Shared- System Maintainers			Other
		A	B				F I S S	M C S	V M S	
10117 - 03.1	Effective for dates of service on or after January 18, 2017, contractors shall cover leadless pacemakers through CED when procedures are performed in CMS-approved CED studies.		X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility						
		A/B MAC			H H H	M A C	D M E	C E D I
		A	B	F I S S				
10117 - 03.2	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X	X					

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Wanda Belle, 410-786-7491 or wanda.belle@cms.hhs.gov (Coverage) , Patricia Brocato-Simons, 410-786-0261 or patricia.brocato-simons@cms.hhs.gov (Coverage) , David Dolan,

410-786-3365 or david.dolan@cms.hhs.gov (Coverage) , Sarah Fulton, 410-786-2749 or sarah.fulton@cms.hhs.gov (Coverage) , Yvette Cousar, 410-786-2160 or yvette.cousar@cms.hhs.gov (Professional Claims) , Valeri Ritter, 410-786-8652 or valeri.ritter@cms.hhs.gov (Institutional Claims)

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

Medicare National Coverage Determinations Manual Chapter 1, Part 1(Sections 10-80.12)

Table of Contents (Rev.201, Issued: 07-28-17)

20.8.4 Leadless Pacemakers

20.8.4 Leadless Pacemakers

(Rev. 201, Issued: 07-28-17, Effective: 01-18-18, Implementation: 08-29-17- for MAC local edits; January 2, 2018 - for MCS shared edits)

A. General

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.

B. Nationally Covered Indications

Effective January 18, 2017, 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>).

- a. 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.*
- b. The rationale for the study is well supported by available scientific and medical evidence.*
- c. 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, to the address below. The information will be reviewed, and approved studies will be identified on the CMS website.

*Director, Coverage and Analysis Group
Re: Leadless Pacemakers CED
Centers for Medicare & Medicaid Services (CMS)
7500 Security Blvd., Mail Stop S3-02-01
Baltimore, MD 21244-1850*

Email address for protocol submissions: clinicalstudynotification@cms.hhs.gov

Email subject line: “CED [NCD topic (i.e. Leadless Pacemakers)] [name of sponsor/primary investigator]”

C. Nationally Non-Covered Indications

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

D. Other

NA

(This NCD last reviewed January 2017.)