

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 3815	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.

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	32/Table of Contents
N	32/380/Leadless Pacemaker
N	32/380.1/Leadless Pacemaker Coding and Billing Requirements for Professional Claims
N	32/380.1.1/Leadless Pacemaker Place of Service Restrictions
N	32/380 1.2/Leadless Pacemaker Modifier
N	32/380.1.3/Leadless Pacemaker Additional Claim of Billing Information
N	32/380.2/ Leadless Pacemaker Claim Adjustment Reason Codes (CARC), Remittance Advice Remark Codes (RARC) and Medicare Summary Notice (MSN) Messages

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

Pub. 100-04	Transmittal: 3815	Date: July 28, 2017	Change Request: 10117
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SUBJECT: National Coverage Determination (NCD20.8.4): Leadless Pacemakers

EFFECTIVE DATE: January 18, 2017

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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 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		D M E	Shared- System Maintainers				Other		
		A	B		H H H	M A C	F I S S	M C S		V M S	C W F
10117 - 04.1	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								
10117 - 04.2	Effective for dates of service on or after January 18, 2017, contractors shall allow payment for leadless pacemakers with CED when billed using the following CPT codes: 0387T Transcatheter insertion or replacement of permanent leadless pacemaker, ventricular 0389T 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, leadless pacemaker system. 0390T Peri-procedural device evaluation (in person) and programming of device system parameters before or after surgery, procedure or test with analysis, review and report, leadless pacemaker system. 0391T Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording and disconnection per patient encounter, leadless pacemaker system.		X								
10117 - 04.3	Effective for dates of service on or after January 18, 2017, contractors shall only pay claims for leadless pacemakers when services are provided in one of the following places of service (POS): POS 06 – Indian Health Service Provider Based Facility POS 21 – Inpatient Hospital POS 22 - On Campus-Outpatient Hospital		X								

Number	Requirement	Responsibility									
		A/B MAC		H H H	D M E M A C	Shared- System Maintainers				Other	
		A	B			F I S S	M C S	V M S	C W F		
	POS 26 – Military Treatment Facility										
10117 - 04.3.1	<p>Effective for dates of service on or after January 18, 2017, contractors shall deny claim lines for leadless pacemakers that do not contain one of the POS codes in 10117-04.3 and use the following messages:</p> <p>CARC 58:</p> <p>“Treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.”</p> <p>RARC N386: “This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at http://www.cms.hhs.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.”</p> <p>MSN 21.25: “This service was denied because Medicare only covers this service in certain settings.”</p> <p>Spanish Version: El servicio fue denegado porque Medicare solamente lo cubre en ciertas situaciones."</p> <p>Group Code –Contractual Obligation (CO).</p>		X								
10117 - 04.4	<p>Effective for dates of service on or after January 18, 2017, contractors shall pay for professional claim detail lines with the procedure codes listed in 10117-04.2 when billed with modifier Q0 – Investigational clinical service provided in a clinical research study that is an approved clinical research study and ICD-10 diagnosis Z00.6: Encounter for examination for normal comparison and control in clinical research program.</p>		X				X				

Number	Requirement	Responsibility								Other
		A/B MAC		D M E	Shared- System Maintainers					
		A	B		H H H	M A C	F I S S	M C S	V M S	
10117 - 04.4.1	<p>Effective for dates of service on or after January 18, 2017, contractors shall return claims as unprocessable with the procedure codes listed in 10117-04.2 billed without modifier -Q0 and use the following messages:</p> <p>CARC 4: “The procedure code is inconsistent with the modifier used or a required modifier is missing. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.”</p> <p>RARC N572: This procedure not payable unless appropriate non-payable reporting.</p> <p>Group Code – Contractual Obligation (CO).</p>		X							
10117 - 04.4.2	<p>Effective for dates of service on or after January 18, 2017, contractors shall return claims as unprocessable with the procedure codes listed in 10117-04.2 billed without ICD-10 Z00.6 and use the following messages:</p> <p>CARC 16 - Claim/service lacks information or has submission/billing error(s) which is needed for adjudication. Do not use this code for claims attachment(s)/other documentation. At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.) Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.</p> <p>RARC M76 - Missing/incomplete/invalid diagnosis or condition.</p> <p>Group Code – Contractual Obligation (CO).</p>		X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			D M E	C E D I
		A	B	H H H		
10117 - 04.7	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): David Dolan, 410-786-3365 or david.dolan@cms.hhs.gov (Coverage) , Sarah Fulton, 410-786-2749 or sara.fulton@cms.hhs.gov (Coverage) , 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) , 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 Claims Processing Manual

Chapter 32 – Billing Requirements for Special Services

Table of Contents
(Rev.3815, Issued: 07-28-17)

Transmittals for Chapter 32

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380.1.1 - Leadless Pacemaker Place of Service Restrictions

380.1.2 - Leadless Pacemaker Modifier

380.1.3 - Leadless Pacemaker Additional Claim Billing Information

380.2 - Leadless Pacemaker Claim Adjustment Reason Codes (CARC), Remittance Advice Remark Codes (RARC) and Medicare Summary Notice (MSN) Messages

380 Leadless Pacemakers

(Rev. 3815, Issued: 07-28-17, Effective: 01-18-18, Implementation: 08-29-17 - for MAC local edits; January 2, 2018 - for MCS shared edits)

Effective for dates of service on or after January 18, 2017, contractors shall cover leadless pacemakers through Coverage with Evidence Development (CED) when procedures are performed in CMS-approved CED studies. Please refer to the National Coverage Determinations Manual (Publication 100-03, Section 20.8.4) for more information.

380.1 Leadless Pacemaker Coding and Billing Requirements for Professional Claims

(Rev. 3815, Issued: 07-28-17, Effective: 01-18-18, Implementation: 08-29-17 - for MAC local edits; January 2, 2018 - for MCS shared edits)

Effective for dates of service on or after January 18, 2017, contractors shall allow the following procedure codes on claims for leadless pacemakers:

0387T Transcatheter insertion or replacement of permanent leadless pacemaker, ventricular

0389T 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, leadless pacemaker system.

0390T Peri-procedural device evaluation (in person) and programming of device system parameters before or after surgery, procedure or test with analysis, review and report, leadless pacemaker system.

0391T Interrogation device evaluation (in person) with analysis, review and report, includes connection, recording and disconnection per patient encounter, leadless pacemaker system.

Effective for dates of service on or after January 18, 2017, contractors shall allow the following ICD-10 diagnosis codes on claims for leadless pacemakers:

Z00.6 – Encounter for examination for normal comparison and control in clinical research program.

380.1.1 Leadless Pacemaker Place of Service Restrictions

(Rev. 3815, Issued: 07-28-17, Effective: 01-18-18, Implementation: 08-29-17 - for MAC local edits; January 2, 2018 - for MCS shared edits)

Effective for dates of service on or after January 18, 2017, contractors shall only pay claims for leadless pacemakers when services are provided in one of the following places of service (POS):

POS 06 – Indian Health Service Provider Based Facility

POS 21 – Inpatient Hospital

POS 22 - On Campus-Outpatient Hospital

POS 26 – Military Treatment Facility

380.1.2 Leadless Pacemaker Modifier

(Rev. 3815, Issued: 07-28-17, Effective: 01-18-18, Implementation: 08-29-17 - for MAC local edits; January 2, 2018 - for MCS shared edits)

Effective for claims with dates of service on or after January 18, 2017, modifier Q0 – Investigational clinical service provided in a clinical research study that is an approved clinical research study, must also be included.

380.1.3 Leadless Pacemaker Additional Claim Billing Information

(Rev. 3815, Issued: 07-28-17, Effective: 01-18-18, Implementation: 08-29-17 - for MAC local edits; January 2, 2018 - for MCS shared edits)

The professional claim must also contain the 8-digit clinical trial identifier in item 23 of the CMS-1500 form or the electronic equivalent.

380.2 Leadless Pacemaker Claim Adjustment Reason Codes (CARC), Remittance Advice Remark Codes (RARC) and Medicare Summary Notice (MSN) Messages Applicable for Professional Claims Only

(Rev. 3815, Issued: 07-28-17, Effective: 01-18-18, Implementation: 08-29-17 - for MAC local edits; January 2, 2018 - for MCS shared edits)

- *Effective for claims with dates of service on or after January 18, 2017, contractors shall deny professional claim lines for leadless pacemakers that do not contain an appropriate POS code and use the following messages:*

CARC 58: “Treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.”

RARC N386: “This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at <http://www.cms.hhs.gov/mcd/search.asp>. If you do not have web access, you may contact the contractor to request a copy of the NCD.”

MSN 21.25: “This service was denied because Medicare only covers this service in certain settings.”

Spanish Version: El servicio fue denegado porque Medicare solamente lo cubre en ciertas situaciones.”

Group Code –Contractual Obligation (CO).

- *Effective for dates of service on or after January 18, 2017, contractors shall return claims with the procedure codes listed in 380.2 billed without modifier Q0 and use the following messages:*

CARC 4: “The procedure code is inconsistent with the modifier used or a required modifier is missing. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.”

RARC N572: This procedure not payable unless appropriate non-payable reporting.

Group Code – Contractual Obligation (CO).

- *Effective for dates of service on or after January 18, 2017, contractors shall return claims as unprocessable with the procedure codes listed in 10117-04.2 billed without ICD-10 Z00.6 and use the following messages:*

CARC 16 - Claim/service lacks information or has submission/billing error(s) which is needed for adjudication. Do not use this code for claims attachment(s)/other documentation. At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.) Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.

RARC M76 - Missing/incomplete/invalid diagnosis or condition.

- *Effective for claims with dates of service on or after January 18, 2017, contractors shall return claims as unprocessable that are billed with the Q0 modifier and do not contain the 8-digit clinical trial identifier in item 23 of the CMS-1500 form or the electronic equivalent. Use the following messages:*

CARC 16: "Claim/service lacks information which is needed for adjudication. At least one Remark Code must be provided (may be comprised of either the NCPDP Reject Reason Code, or Remittance Advice Remark Code that is not an ALERT.)"

RARC MA50: Missing/incomplete/invalid Investigational Device Exemption number or Clinical Trial number.

Group Code – Contractual Obligation (CO).