



National Coverage Determination (NCD 20.8.4): Leadless Pacemakers

MLN Matters Number: MM10117

Related Change Request (CR) Number: 10117

Related CR Release Date: July 28, 2017

Effective Date: January 18, 2017

Related CR Transmittal Number:
R201NCD and R3815CP

Implementation Date: August 29, 2017 for
local MAC system edits and January 2,
2018 for shared system edits

PROVIDER TYPES AFFECTED

This MLN Matters Article is intended for physicians and other providers who submit claims to Medicare Administrative Contractors (MACs) for leadless pacemaker services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

Change Request (CR) 10117 informs MACs that effective January 18, 2017, the Centers for Medicare & Medicaid Services (CMS) covers leadless pacemakers through Coverage with Evidence Development (CED) when procedures are performed in CMS-approved CED studies. Please make your billing staffs aware of this determination.

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 currently no National Coverage Determination (NCD) in effect.

On January 18, 2017, CMS issued an NCD to cover leadless pacemakers through CED. CMS covers leadless pacemakers when procedures are performed in studies approved by the Food and Drug Administration (FDA). 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.

For such coverage, Medicare will allow payment for claims for dates of service on or after January 18, 2017 for leadless pacemakers through CED when billed with 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.

Effective for dates of service on or after January 18, 2017, MACs will 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.

Effective for dates of service on or after January 18, 2017, contractors shall return claims as unprocessable with the listed procedure codes 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, modifier **Q0** – Investigational clinical service provided in a clinical research study that is an approved clinical research study, must also be included.

Effective for dates of service on or after January 18, 2017, MACs will return claims with the procedure codes listed 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).

Remember to include the 8-digit clinical trial identifier on the claim. Effective for claims with dates of service on or after January 18, 2017, MACs will 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).

Effective for dates of service in or after January 18, 2017, MACs 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

Where the proper POS code is not included and the claim is rejected/denied, the following messaging should be used:

- 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 www.cms.hhs.gov/mcd/search.asp. If you do have web access, you may contact the contractor to request a copy of the NCD.
- Group Code – Contractual Obligation (CO)

MACs will not search their files for claims for leadless pacemakers with dates of service between January 18, 2017, and the implementation date of CR10117, but may adjust claims that you bring to their attention.

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 <http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/index.html>. The process for submitting a clinical research study to Medicare is outlined in the NCD.

Leadless pacemakers are non-covered outside of CMS-approved studies.

Note: This revision to the Medicare NCD Manual is a National Coverage Determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, and MACs with the Federal government

that review and/or adjudicate claims, determinations, and/or decisions, quality improvement organizations, qualified independent MACs, 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).

ADDITIONAL INFORMATION

The official instruction, CR10117, issued to your MAC regarding this change consists of two transmittals. The first is available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R3815CP.pdf> and the second is at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R201NCD.pdf>.

If you have any questions, please contact your MAC at their toll-free number. That number is available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/>.

DOCUMENT HISTORY

Date of Change	Description
August 1, 2017	Initial article released.

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