DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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Related CR Transmittal #: R192NCD and R3515CP

Implementation Date: October 3, 2016

Percutaneous Left Atrial Appendage Closure (LAAC)

Provider Types Affected

This MLN Matters® Article is intended for physicians, other providers, and suppliers submitting claims to Medicare Administrative Contractors (MACs) for services provided to Medicare beneficiaries.

Provider Action Needed

Change Request (CR) 9638 informs MACs that the Centers for Medicare & Medicaid Services (CMS) issued a National Coverage Determination (NCD) covering percutaneous Left Atrial Appendage Closure (LAAC) through Coverage with Evidence Development (CED) when LAAC is furnished in patients with Non-Valvular Atrial Fibrillation (NVAF) and the device has received Food and Drug Administration (FDA) Premarket Approval (PMA) for that device's FDA-approved indication and meets all the specified conditions. Make sure that your billing staffs are aware of these changes.

Background

LAAC is a strategy to reduce the risk of stroke by closing the Left Atrial Appendage (LAA) in patients with NVAF. Patients with NVAF, an abnormally rapid, irregular heartbeat, are at an increased risk of stroke. Some evidence suggests that many of the strokes attributed to NVAF originate from the LAA. The LAA is a tubular structure that opens into the left atrium of the heart. LAAC with a percutaneously implanted device could be used in patients with

NVAF to reduce cardioembolic stroke risk as a potential alternative to oral anticoagulation.

On February 8, 2016, CMS issued an NCD covering percutaneous LAAC through CED when LAAC is furnished in patients with NVAF and the device has received FDA PMA for that device's FDA-approved indication and meets all the specified conditions. Coverage requires that patients must have:

- A CHADS2 score ≥ 2 (Congestive heart failure, Hypertension, Age >75, Diabetes, Stroke/transient ischemia attack/thromboembolism) or CHA2DS2-VASc score ≥ 3 (Congestive heart failure, Hypertension, Age ≥ 65, Diabetes, Stroke/transient ischemia attack/thromboembolism, Vascular disease, Sex category)

- A formal shared decision making interaction with an independent non-interventional physician using an evidence-based decision tool on oral anticoagulation in patients with NVAF prior to LAAC. Additionally, the shared decision making interaction must be documented in the medical record

- A suitability for short-term warfarin but deemed unable to take long term oral anticoagulation following the conclusion of shared decision making, as LAAC is only covered as a second line therapy to oral anticoagulants

The NCD lists the criteria for the physician and facility criteria and includes a requirement for a multidisciplinary team to be engaged in patient care.

The patient must be enrolled in, and the multidisciplinary team (MDT) and hospital must participate in a prospective, national, audited registry that: 1) consecutively enrolls LAAC patients and 2) tracks the specified annual outcomes for each patient for a period of at least four years from the time of the LAAC. The registry must address pre-specified research questions, adhere to standards of scientific integrity, and be approved by CMS. Approved registries will be posted at **https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/LAAC.html**. The process for submitting a registry to Medicare is outlined in the NCD.

For devices and indications that are not approved by FDA, patients must be enrolled in a qualifying FDA-approved Randomized Controlled Trial (RCT). The clinical study must address pre-specified research questions, adhere to standards of scientific integrity, and be approved by CMS. Approved studies will be posted at **https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/LAAC.html**. The process for submitting a clinical research study to Medicare is outlined in the NCD.

LAAC claims with dates of service on or after February 8, 2016, will be billed with temporary level III CPT code 0281T (percutaneous transcatheter closure of the left atrial appendage with implant, including fluoroscopy, transseptal puncture, catheter placement(s) left atrial angiography, left atrial appendage angiography, radiological supervision and interpretation) and will be MAC-priced. CMS will issue further instructions, once a permanent CPT level 1 replaces the temporary code.

LAAC is non-covered for the treatment of NVAF when not furnished under CED according to the criteria outlined in the NCD, which is at **https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R192NCD.pdf**.

Additional Billing Instructions

On institutional claims (type of bill 11X), hospitals should show:

- ICD-10 procedure code of 02L73DK (Occlusion of Left Atrial Appendage with Intraluminal Device, Percutaneous Approach)
- A primary diagnosis code of one of the following:
  - I48.0 – Paroxysmal atrial fibrillation
  - I48.1 – Persistent atrial fibrillation
  - I48.2 – Chronic atrial fibrillation
  - I48.91 – Unspecified atrial fibrillation
- A secondary ICD-10 diagnosis code of Z00.6 – Encounter for examination for normal comparison and control in clinical research program
- Condition Code 30 (Qualifying Clinical Trial), and
- Value Code D4 - Clinical Trial Number (assigned by NLM/NIH with an 8-digit clinicaltrials.gov identifier number listed on the CMS website)

MACs will fully reject inpatient claims for LAAC with discharges on or after February 8, 2016, when billed without the appropriate procedure, diagnosis, or clinical trial codes, with the following messages:

- Claim Adjustment Reason Code (CARC) 50: These are non-covered services because this is not deemed a “medical necessity” by the payer.
- Remittance Advice Remarks Code (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.
- Group Code - Contractual Obligation (CO)

Professional claims with dates of service on or after February 8, 2016, for LAAC under CED will be paid only when billed with the following codes:

- CPT 0281T
- Primary ICD-10 diagnosis code (one of the following):

  - I48.0 – Paroxysmal atrial fibrillation,
  - I48.1 – Persistent atrial fibrillation,
  - I48.2 – Chronic atrial fibrillation,
  - I48.91 – Unspecified atrial fibrillation
- Place of Service code of 21 (inpatient hospital)
- Secondary diagnosis code Z00.6
- Modifier Q0
- Clinical trial number in item 23 of the CMS-1500 form or electronic equivalent

MACs will deny LAAC claims when billed without the appropriate diagnosis codes, with the following messages:

- CARC 50 - These are non-covered services because this is not deemed a "medical necessity" by the payer. 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.
- Group Code – Contractual Obligation (CO).

MACs will deny claims for LAAC with 0281T with a POS code other than 21 using 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."
- Group Code – Contractual Obligation (CO).

MACs will return claim lines on professional claims for 0281T as unprocessable when the Q0 modifier is not present using 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."
- Group Code – Contractual Obligation (CO)

MACs will return claim lines with 0281T as unprocessable when billed without secondary diagnosis code Z00.6 using 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 M76: "Missing/incomplete/invalid diagnosis or condition."
- Group Code – Contractual Obligation (CO)

Finally, failure to include the clinical trial number will result in MACs returning claim lines as unprocessable using 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)

Note that MACs will not search their files for claims for LAAC with dates of service on or after February 8, 2016, that were processed prior to implementation of CR9638. However, they will adjust such claims that you bring to their attention.

Additional Information

The official instruction, CR9638, consists of two transmittals. The first contains the actual NCD and is available at **https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R192NCD.pdf**. The second provides the claims processing instructions and it is at available at **http://www.cms.hhs.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3515CP.pdf**.

If you have any questions, please contact your MAC at their toll-free number. That number is available at **http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/index.html** under - How Does It Work.