CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 3515	**Date: May 6, 2016**
	Change Request 9638

SUBJECT: Percutaneous Left Atrial Appendage Closure (LAAC)

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to inform contractors 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 Fibrilation (NVAF) and according to an FDA approved indication for percutaneous LAAC with an FDA-approved device.

EFFECTIVE DATE: February 8, 2016
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: October 3, 2016

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
N/A	N/A

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

Attachment - Business Requirements

Pub. 100-04	Transmittal: 3515	Date: May 6, 2016	Change Request: 9638

SUBJECT: Percutaneous Left Atrial Appendage Closure (LAAC)

EFFECTIVE DATE: February 8, 2016
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I. GENERAL INFORMATION

A. Background: Left atrial appendage closure (LAAC) is a strategy to reduce the risk of stroke by closing the left atrial appendage (LAA) in patients with non-valvular atrial fibrillation (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.

B. Policy: On February 8, 2016, the Centers for Medicare & Medicaid Services (CMS) issued a National Coverage Determination (NCD) covering percutaneous LAAC through Coverage with Evidence Development (CED) when LAAC is furnished in patients with NVAF and according to an FDA approved indication for percutaneous LAAC with an FDA-approved device. 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 and includes a requirement for a multidisciplinary team to be engaged in patient care.

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 on the CMS website 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 is non-covered for the treatment of NVAF when not furnished under CED according to the criteria 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 contractor-priced. Once a permanent CPT level 1 replaces the above code, CMS will issue instructions for the permanent CPT level 1 code in a future CR.

NOTE: The Publication 100-04 Claims Processing Manual will not be updated. Please refer to the Publication 100-03 National Coverage Determination manual, section 20.34 Percutaneous Left Atrial Appendage Closure (LAAC) for policy information.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
9638 - 04.1	Effective February 8, 2016, contractors shall cover percutaneous LAAC through Coverage with Evidence Development (CED) when LAAC is furnished in patients with NVAF and according to an FDA approved indication for percutaneous LAAC with an FDA-approved device. Please refer to NCD Manual Section 20.34 for policy.	X								
9638 - 04.2	Effective for inpatient hospital (TOB 11X) discharges on or after February 8, 2016, contractors shall allow payment for LAAC under CED only when billed with the following codes: ICD-10 procedure code: 02L73DK – Occlusion of Left Atrial Appendage with Intraluminal Device, Percutaneous Approach Primary ICD-10 diagnosis code (one of the following): I48.0 – Paroxysmal atrial fibrillation, I48.1 – Persistent atrial fibrillation, I48.2 – Chronic atrial fibrillation, OR	X				X				

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	I48.91 – Unspecified atrial fibrillation Secondary ICD-10 diagnosis code: Z00.6 – Encounter for examination for normal comparison and control in clinical research program Condition Code 30 – Qualifying Clinical Trial Value Code D4 – Clinical Trial Number (assigned by NLM/NIH with an 8-digit clinicaltrials.gov identifier number listed on the CMS website)									
9638 - 04.2.1	Contractors shall fully reject inpatient hospital 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: CARC 50: These are non-covered services because this is not deemed a “medical necessity” by the payer. 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) MSN 15.20: The following policies [NCD 20.34] were used when we made this decision Spanish Version: MSN 15.20: Las siguientes políticas [NCD 20.34], fueron utilizadas cuando se tomó esta decisión.	X								
9638 - 04.3	Effective for claims with dates of service on or after February 8, 2016, contractors shall allow		X				X			

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	payment for LAAC under CED 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, OR I48.91 – Unspecified atrial fibrillation									
9638 - 04.3.1	Effective on or after February 8, 2016, contractors shall deny claims for LAAC 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). MSN 16.77 – This service/item was not covered because it was not provided as part of a qualifying trial/study. (Este servicio/artículo no fue cubierto porque no estaba incluido como parte de un ensayo		X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	clínico/estudio calificado.) MSN 15.20 – The following policies [NCD 20.34] were used when we made this decision. (Las siguientes políticas [NCD 20.34] fueron utilizadas cuando se tomó esta decisión.									
9638 - 04.4	Effective for dates of service on or after February 8, 2016, contractors shall pay claims for 0281T only when services are provided for in place of service (POS) 21, Inpatient Hospital.		X							
9638 - 04.4.1	Effective on or after February 8, 2016, contractors shall deny claims lines with 0281T with a POS code other than 21. Claim Adjustment Reason Code (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." Remittance advice remark 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." Medicare Summary Notice (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).		X							
9638 - 04.5	Effective for dates of service on or after February 8, 2016, contractors shall pay claim lines for 0281T in a clinical research study when billed with modifier Q0, Investigational clinical service		X				X			

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	provided in a clinical research study that is in an approved clinical research study.									
9638 - 04.5.1	Effective for dates of service on or after February 8,2016, contractors shall return the claim lines for 0281T in a clinical trial as unprocessable when billed without a Q0 modifier. 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).		X							
9638 - 04.6	Effective for dates of service on or after February 8,2016, contractors shall pay claim lines for 0281T in a clinical trial when billed with secondary diagnosis code Z00.6.		X				X			
9638 - 04.6.1	Effective for dates of service on or after February 8, 2016, contractors shall return claim lines for 0281T in a clinical research study as unprocessable when billed without secondary diagnosis code Z00.6. 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).		X							
9638 - 04.6.2	Effective for dates of service on or after February 8, 2016, contractors shall return claims billed with modifier Q0 that do not contain a clinical trial		X							

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	number in item 23 of the CMS-1500 form or the electronic equivalent. 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).									
9638 - 04.7	Contractors shall not search their files for LAAC claims with dates of service between February 8, 2016 and the implementation date of this change request, but may adjust claims that are brought to their attention.	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
9638 - 04.8	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	X	X			

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	information that would benefit their provider community in billing and administering the Medicare program correctly.					

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): Mark Baldwin, 410-786-8139 or Mark.Baldwin@cms.hhs.gov (Professional Claims) , Kimberly Long, 410-786-5702 or Kimberly.long@cms.hhs.gov (Coverage and Analysis) , Felicia Rowe, 410-786-5655 or Felicia.Rowe@cms.hhs.gov (Institutional Claims) , Wanda Belle, 410-786-7491 or Wanda.Belle@cms.hhs.gov (Coverage and Analysis) , Patricia Brocato-Simons, 410-786-0261 or Patricia.BrocatoSimons@cms.hhs.gov (Coverage and Analysis)

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

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
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ATTACHMENTS: 0