The CONFORM Pivotal Trial

An Evaluation of the Safety and Effectiveness of the Conformal CLAAS System for Left Atrial Appendage Occlusion

CLINICAL STUDY REIMBURSEMENT GUIDE

IDE# G180189
NCT05147792

Sponsored By
Conformal Medical, Inc.
15 Trafalgar Square, Ste. 101
Nashua, NH 03063

Investigational Device: CLAAS System

Control Devices: Commercially available Boston Scientific WATCHMAN device, WATCHMAN FLX and Abbott Laboratories, Amulet device

Disclaimer

Conformal Medical, Inc. does not guarantee that Medicare or any public or private payer will cover any products or services at any particular level and specifically excludes any representation or warranty relating to reimbursement. Laws, regulations, and payer policies concerning reimbursement are complex and change frequently, and service providers are responsible for all decisions relating to coding and reimbursement submissions. Payor policies will vary and should be verified for limitations on diagnosis, coding or site of service requirements prior to treatment. The coding options listed within this guide are commonly used codes and are not intended to be an all-inclusive list. Accordingly, Conformal Medical strongly recommends that you consult with your payers, reimbursement specialist and/or legal counsel regarding coding, coverage and payment matters.

Contents

1 Introduction

Conformal Medical, Inc. is pleased to offer this IDE Clinical Study Reimbursement Guide for the Investigators and their staff participating in the CONFORM Study. This Category B IDE clinical study[1] is eligible for Medicare coverage approval from the Centers for Medicare and Medicaid Services' (CMS) central office under Coverage with Evidence Development (CED).[2] Additionally, Medicare coverage for the routine services provided in the CONFORM Study are eligible for payment under CMS' NCD for Routine Costs in Clinical Trials (310.1).[3]

The purpose of this document is to provide CONFORM study centers with the following information:

- Overview of CMS' Coverage with Evidence Program – Section 2A
- Applicable CMS National Coverage Determinations Policies – Section 2B
- Details on CMS' coverage approval status for the CONFORMAL Study – Section 3A
- Process for notification of IDE study participation to local A/B MACs – Section 3B
- Instructions for submitting Medicare claims for the study – Section 4
- Background on private payer coverage and pre-authorization – Section 6
- Summary of possible billing codes for study-related items/services – Appendix B

Please consider carefully the information provided in the following pages supporting appropriate, timely payer coverage, billing, and payment for the CONFORM Study. Copies of its contents may be provided to hospital and physician billing, chargemaster, and compliance staff as necessary.

For assistance regarding the contents of this guide: Email your questions to payments@conformalmedical.com.

2 Policy Background

A. Coverage with Evidence Development (CED)

CED is a paradigm whereby Medicare covers items and services on the condition that they are furnished in the context of approved clinical studies or with the collection of additional clinical data. In making coverage decisions involving CED, CMS decides after a formal review of the medical literature to cover an item or service only in the context of an approved clinical study or when additional clinical data are collected to assess the appropriateness of an item or service for use with a particular beneficiary. Although Medicare generally does not cover experimental or investigational items and services as reasonable and necessary under section 1862(a)(1)(A) of the Act, the Medicare program has adopted coverage policies that relate to clinical studies before the formal articulation in 2006 of the CED paradigm. In 1995, CMS (then known as HCFA) established coverage for certain items furnished in FDA-approved IDE trials. CMS updated the coverage criteria for certain items and services in IDE trials effective January 1, 2015. In response to a June 7, 2000 Executive Memorandum, CMS (then HCFA) issued an NCD for coverage under the authority of section 1862(a)(1)(E) of routine costs in clinical trials, commonly referred to as the Clinical Trial Policy. The Clinical Trial Policy was revised in 2007 through the NCD reconsideration process.[2]

In 2005, CMS began to implement NCDs requiring study participation. Coverage in the context of ongoing clinical research protocols or with additional data collection can expedite earlier beneficiary access to innovative technology while ensuring that systematic patient safeguards, including assurance that the technology is provided to clinically appropriate patients, are in place to reduce the risks inherent to new technologies, or to new applications of older technologies. More recent NCDs have tended to rely on section 1862(a)(1)(E) of the Act, in which CED is used to support clinical research. Under CED, routine costs of an approved clinical trial in both the treatment arm and the control (standard of care or placebo) arm are paid. Routine costs include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, coverage is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial.[2]

B. Applicable CMS National Coverage Determination (NCD) Policies

1. NCD for Percutaneous Left Atrial Appendage Closure (LAAC) (20.34) [4]

The Centers for Medicare & Medicaid Services (CMS) covers percutaneous LAAC for non-valvular atrial fibrillation (NVAF) through Coverage with Evidence Development (CED) with the following conditions:

- **a.** LAAC devices are covered when the device has received FDA Premarket Approval (PMA) for that device's FDA-approved indication and meet all of the conditions stated within Section A of NCD 20.34.
- **b.** LAAC is covered for NVAF patients not included in Section A. of this decision when performed within an FDA-approved randomized controlled trial (RCT) if such trials meet the criteria established below:

As a fully-described written part of its protocol, the RCT must critically answer, in comparison

to optimal medical therapy, the following questions:

- As a primary endpoint, what is the true incidence of ischemic stroke and systemic embolism?
- As a secondary endpoint, what is cardiovascular mortality and all-cause mortality?

FDA-approved RCTs must be reviewed and approved by CMS. Consistent with section 1142 of the Act, AHRQ supports clinical research studies that CMS determines address the above-listed research questions and the a-m criteria listed in Section c. of this decision. LAAC is non-covered for the treatment of NVAF when not furnished under CED according to the above-noted criteria.[4] [*Excerpt*]

2. NCD for Routine Costs in Clinical Trials (310.1) [3]
This policy does not withdraw Medicare coverage for items and services that may be covered according to -- the regulations on category B investigational device exemptions found in 42 CFR 405.201-405.215, 411.15, and 411.406. Medicare covers -- reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply.[3] [*Excerpt*]

C. Medicare Advantage (For patients opting for benefits with a Medicare-approved HMO)

An MA organization (MAO) offering an MA plan must provide enrollees in that plan with all Part A and Part B, Original Medicare services. In National Coverage Determinations (NCDs) requiring CED, Medicare covers items and services in CMS-approved CED studies. **MAOs are responsible for payment of items and services in CMS approved CED studies** unless CMS determines that the significant cost threshold is exceeded for that item or service (see 42 CFR 422.109). Approved CED studies are posted on the CMS Coverage with Evidence Development webpage. Billing instructions are issued for each NCD.[6]

3 Medicare Coverage

A. Coverage with Evidence Development (CED) Approval

CMS issued a Medicare National Coverage Determination (NCD) on February 8, 2016 which allows for coverage of LAAC under Coverage with Evidence Development (CED) with certain conditions.[5]

FDA-approved RCTs must be reviewed and approved by CMS. Consistent with section 1142 of the Act, AHRQ supports clinical research studies that CMS determines address the research questions and the criteria listed in this decision.

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 listed in this decision.[4] [*Excerpt*]

What does this mean for the CONFORM Study?

Conformal Medical submitted this IDE study to the CMS central office for review under the coverage criteria outlined within the NCD for Percutaneous Left Atrial Appendage Closure (LAAC) (20.34). Conformal Medical received Medicare coverage approval **effective March 23, 2022**. Medicare coverage approval of this IDE study applies to all participating sites located within all Medicare jurisdictions.

CMS maintains a list of approved studies under NCD 20.34 (LAAC) for study sponsors, providers, and MACs. Sites may consult this webpage to validate whether the CONFORM Study has been CMS-approved for Medicare coverage. See: https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/LAAC

***Important**: This webpage is different from the central CMS "Approved IDE Studies" webpage. CMS approved CED studies are posted on their own NCD specific webpages.

B. Site notification of IDE Study Participation (if required)

Most sites will need to submit a **"Notification of IDE study participation"** to their local Part A/B MAC. This process does not involve a request for local Medicare IDE coverage review/approval. Rather, A/B MAC notification is necessary to ensure proper claims processing for study-related Medicare patient claim submissions.

A/B MAC notification requirements vary by jurisdiction and typically include providing the site's physician and facility provider numbers (e.g., NPI, PTAN) along with the study's IDE number and national clinical trial (NCT) ID from clinicaltrials.gov. To avoid claim rejections, site notifications should be submitted to the local A/B MAC before seeking payment for individual Medicare patients in this study.

Note: See Appendix A for list of A/B MACs jurisdictions that require site notification of IDE study participation along with a summary of MAC specific policies and weblinks.

4 Medicare Claims

Investigational devices and their related routine care items and services provided in Medicare-approved CED studies are also subject to the Medicare billing requirements for "special services" outlined below. *Please note that the following information is for patients randomized to the Claas Device System. Please follow standard billing procedures for patients enrolled in the control arm.*

A. Category B IDE Device Services (Physician Claims):

Physician Billing on Form CMS-1500[7]
Remarks (Field 19): Report NCT# 05147792, the study's 8-digit National Clinical Trial ID
Diagnosis Code (Field 21): Report ICD-10 code 'Z00.6' (*Encounter for examination for normal comparison and control in clinical research program*)
Prior Authorization # (Field 23): Enter the study's FDA IDE number 'G180189'
Modifier (Field 24.D): Append HCPCS modifier *'Q0'* (*Investigational clinical service*) to the investigational device implant procedure code(s); Append modifier *'Q1'* (*Routine clinical service*) to the routine patient care procedure code(s) billed on the same claim and all future claims related to study participation

B. Category B IDE Devices (Hospital Claims):

Hospital Billing on Form CMS-1450 (UB-04)[7]
Condition Codes (FL 18-28): Use condition code '30' (*Qualifying clinical trial*)
Value Code (FL 39): Enter '03973866' (the study's 8-digit National Clinical Trial ID (NCT#)) in the value amount of value code 'D4' on the paper claim or in Loop 2300, REF02, REF01=P4 (do not use 'CT' on the electronic claim)
Revenue Code (FL 42): Use revenue code '0624' (*Investigational Device*), which is an extension of revenue code 027X (*Medical/Surgical Supplies*)
Description (FL 43 - 0624 revenue code line): Enter the study's FDA IDE number 'G180189'[9]
Modifier (FL 44): Append HCPCS modifier *'Q1'* to all lines that contain a routine service (Outpatient claims only) (note: *'Q0'* is not applicable, as the investigational procedure is only performed as an inpatient procedure*)
Diagnosis Code (FL 67): Report ICD-10 code 'Z00.6' (*Encounter for examination for normal comparison and control in clinical research program*) in either the primary/secondary positions

* Left atrial appendage exclusion (33340) is identified as status "C", Inpatient Only

Definitions[8]

Modifier Q0: *Investigational clinical service provided in a clinical research study that is in an approved clinical research study*.

Modifier Q1: *Routine clinical service provided in a clinical research study that is in an approved clinical research study*.

Notes:

- **See Appendix B** for a list of "Commonly Billed Codes" (e.g., CPT®, HCPCS)
- **See Appendix C** to view "Medicare Claim Form Examples" (e.g., CMS-1500, UB-04)

C. Facility Billing for No-Cost Items

Hospital inpatient providers should not bill for the Category B IDE device if receiving the device free-of-charge.

E. Medical Records Documentation Requirements (All Providers)

The billing provider must include in the beneficiary's medical record the following information: trial name, sponsor, and sponsor-assigned protocol number. This information does not need to be submitted with the claim but must be provided if requested for medical review.[7]
For example:

- **Trial Name:** *The CONFORM Study*
- **Sponsor Name:** *Conformal Medical, Inc.*
- **Sponsor-Assigned Protocol** #21-101

5 Medicare Payment

Payment

Medicare typically reimburses for the investigational device and the associated routine care items and services provided in Medicare-approved CED clinical study using its usual payment systems. For example, hospital inpatient payment for the costs of the study device and related services are bundled into the existing Medicare Severity Diagnosis Related Group (MS-DRG) for the admission. Hospital outpatient payments are packaged into one or more applicable Ambulatory Payment Classifications (APC). Physician services are paid via the Medicare Physician Fee Schedule.

6 Private Payer Pre-Authorization

Private Payers (E.g., commercial plan coverage)

Commercial health insurance is any type of health benefit not administered by the government, such as Medicare. The insurance may be employer-sponsored or privately purchased. Private insurers are not bound by Medicare's Category B IDE device coverage regulations and their contracts often vary under each patient's plan. Private payers set their own coverage guidelines for clinical trial participation. For example, some private payers may cover all costs with the exception of the investigational device (E.g., "Routine Patient Costs" otherwise be paid outside of the study), as their contracts may exclude investigational items/service coverage. Some may cover all costs including the investigational device provided if it is considered medically reasonable and necessary. In addition, private insurers may choose to follow the NCD or establish their own policies for LAAC therapy. The following major commercial payer policies address coverage within the context of Category B IDE studies and/or have a policy for LAAC therapy (Click on hyperlinks for full policy details):

- Aetna® (CPB 0466 and CPB 0791)
- Humana® (Policy# HUM-0410-023 (Search "Clinical Trials")
- UnitedHealthcare® Commercial (Policy# CDG.006.13) **|** Community Plan (Policy# CS018.L)

Ultimately, there are numerous private payers and individual plans with variations in coverage rules. Therefore, it is best to determine coverage of Category B IDE study services on a per patient basis. To avoid potential coverage delays, continue to follow each payer's process for gaining pre-authorization. Below are several steps to determine private payer coverage for the IDE device and its related services:

1. Contact payers directly and/or research their written policies to verify coverage guidelines for investigational devices and services
2. Continue to follow usual requirements for referral, network, or other payer requirements
3. Obtain Pre-Authorization according to plan rules (see **Appendix D**) -- For example:
    - Communicate the medical justification (E.g., by providing diagnostic/procedure codes)
    - Disclose that services will be provided within the context of an FDA-approved IDE study
        - Note: some prior-authorization forms have a section or check-box to identify "investigational" items/services that should be utilized
    - Provide additional study details as required by the payer

4. Appeal negative determinations as necessary according to plan rules (see **Appendix E**)

Note: Original Medicare Part A/B does NOT require pre-authorization at the individual patient level. However, many Medicare Advantage (MA) plans and state administered Medicaid programs have pre-authorization requirements that should be followed. Pre-authorization process may take up to 14 days to complete.

7 References

1. FDA Categorization of IDE Devices to Assist CMS with Coverage Decisions (*12/5/2017*)
   - https://www.fda.gov/media/98578/download
2. Centers for Medicare and Medicaid Services: *Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development (11/20/2014)* https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27
3. NCD for Routine Costs in Clinical Trials: *310.1 (07/09/07)*
   - https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/r74ncd.pdf
4. CMS NCD for Percutaneous Left Atrial Appendage Closure (LAAC) (20.34) *(02/08/2016)* https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=367&ncdver=1&NCAId=281&bc=AAAAAAAACAAAAA%3d%3d&
5. Coverage with Evidence Development: Percutaneous Left Atrial Appendage Closure (LAAC) https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/LAAC.html
6. Medicare Managed Care Manual: *Chapter 4 - Benefits and Beneficiary Protections, Sec. 10.2 - Basic Rule (Rev. 121, 04-22-16) ; Sec. 10.7.2 – Investigational Device Exemption (IDE) (Rev. 121, 04-22-16)*
   - https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c04.pdf
7. Medicare Claims Processing Manual: *Chapter 32 - Billing Requirements for Special Services, Section 67.2.1 – Billing No Cost Items Due to Recall, Replacement, or Free Sample (Rev. 3181, 07-06-15), Section 68 - Investigational Device Exemption (IDE) Studies (Rev. 3105, 01-01-15) and Section 69 – Qualifying Clinical Trials (Rev. 487, Issued: 03-04-05)*
   - https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c32.pdf
8. CMS Manual System (Pub 100-04 Medicare Claims Processing): *New HCPCS Modifiers when Billing for Patient Care in Clinical Research Studies (CR 5805, Trans 1418) (01/18/2008)*
   - www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1418CP.pdf

APPENDIX A: PART A/B MAC SITE NOTIFICATION LIST

The following table summarizes the Part A/B MACs requiring individual sites to submit a "Notification of IDE Study Participation". This process is in addition to central CMS' coverage approval. A/B MAC IDE policies frequently change. All Sites should verify current local MAC policies regardless of jurisdiction.

MAC Name (Jurisdiction)	States Covered	IDE Policy Details	Policy/Form Links
CGS (J-15)	KY, OH	*CGS will have the responsibility of providing approval for system updates at the local level; in order to do this we require the documents listed below via J15IDE@cgsadmin.com.* • *Local IRB Approval* • *CMS Approval letter provided to the sponsor* *Along with the above 2 requirements please include a letter with the following information:* • *PTAN of the facility,* • *Name(s) of the principal investigator w/ NPI* • *Names of the sub-investigators with NPI #s*	**CGS Process for INITIAL IDE Submissions:** http://www.cgsmedicare.com/partb/pubs/news/2014/1214/cope27849.html
FCSO (J-N)	Florida	*In order to administer the MAC JN claims for CMS approved studies prior to submission of these claims, the provider must submit a copy of the CMS approval letter to the MAC JN medical policy department (clinicaltrials@fcso.com).*	**IDE process for studies approved by the CMS:** http://medicare.fcso.com/clinical_trials/0297020.asp
Noridian (J-E)	CA, HI, NV	*For IDE trials with an FDA approval letter on or after January 01, 2015 that have been approved by CMS, Noridian will only require**:* *1. Notice of trial participation,* *2. IDE designator assigned by the FDA,* *3. Clinical trial number as listed on clinicaltrials.gov* *A letter [e.g., an email body] including the three above stated requirements along with the PTAN of the facility, the names of the principal investigator, study doctors and their NPIs is to be submitted at time of request.* *All IDE submissions regardless of FDA letter date should be sent to one of the following: Email: iderequests@noridian.com*	**Jurisdictions E/F Process:** IDE Documentation Requirements for Studies with an FDA Approval dated January 01, 2015 or later (A54917) **Note:** click on hyperlink above to open page in web browser. ****Follow the instructions** – "Investigational Device Exemptions (IDE) – IDE Documentation Requirements for Studies with an FDA Approval dated January 01, 2015 or later"
Noridian (J-F)	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY		

<table>
<tr><td>Novitas (J-H)</td><td>AR, CO, LA, MS, NM, OK, TX</td><td rowspan="2">For IDE trials with a FDA approval on or after January 1, 2015 and which have received CMS approval to bill Medicare, Novitas requests certain information be sent to us before Institutional (Part A) claims are submitted. This will allow us to make necessary preparations for receipt of Part A claims.

Novitas requests the following information be <u>faxed</u> to us at 410-891-5231:
CMS Approval Letter including the 6-digit IDE Study and 8-digit National Clinical Trial (NCT) numbers
Cover facsimile sheet including the Name(s) of hospital/facility and their Provider Transaction Access Number(s) (PTAN)
This information will allow Novitas to add information into our Part A claims payment system to ensure proper processing of <u>Part A</u> claims related to these IDE clinical trials.</td><td rowspan="2">Submission Requirements for IDEs that Receive FDA and CMS Approval on or after January 1, 2015:

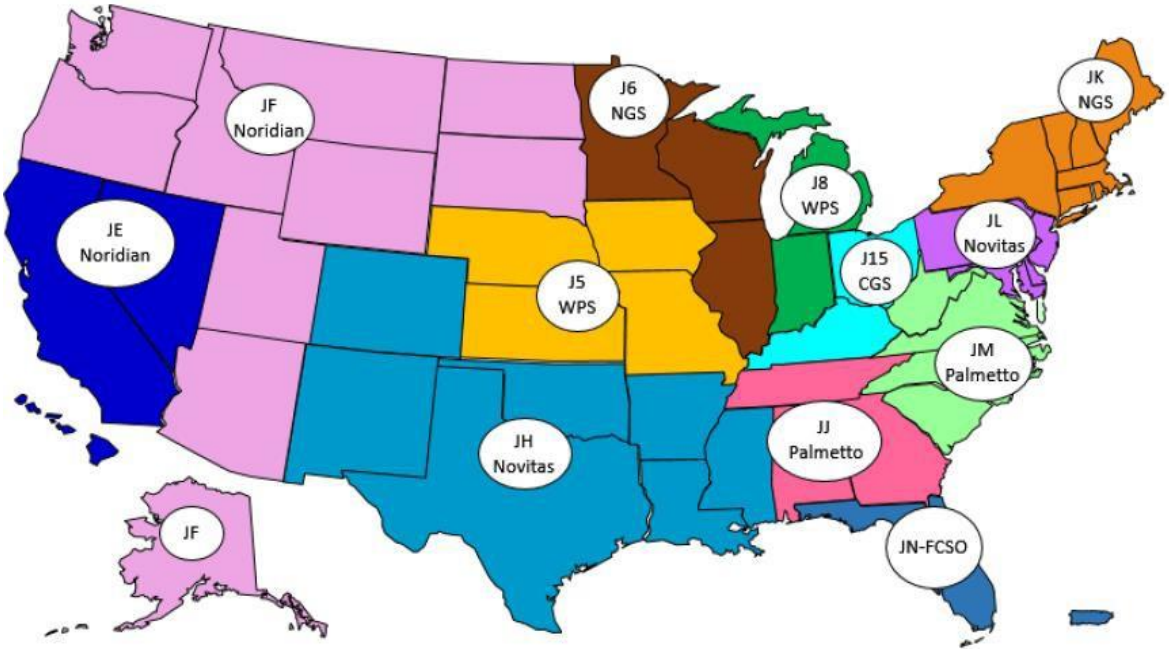
https://www.novitas-solutions.com/

Note: From the homepage first choose your MAC jurisdiction, then perform a Search by the keyword “Investigational” (Click on hyperlink for article titled “Investigational Device Exemption”</td></tr>
<tr><td>Novitas (J-L)</td><td>DC, DE, MD, NJ, PA</td></tr>
<tr><td>NGS (J6)</td><td>IL, MN , WI</td><td rowspan="2">To avoid any delays in claims processing, for IDE studies approved by CMS, please provide the following information to NGS:
IDE number
Copy of CMS Approval Letter
Name and UPIN of facility where services will be provided
Principal Investigator Information (E.g., full name, NPI#)
Please submit all information to NGS by one of the following methods:
Email: NGSIDERequests@anthem.com
Fax: 315-442-4257</td><td rowspan="2">Request Form for Investigational Device Exemptions (IDE) or Carotid Stent Clinical Studies (PMA):
https://www.ngsmedicare.com

Note: From the homepage select Part A or B and your state. Perform a Search by entering the keyword “Investigational”.</td></tr>
<tr><td>NGS (J-K)</td><td>CT, ME, MA, NH, NY, RI, VT</td></tr>
<tr><td>Palmetto (J-J)</td><td>AL, GA, TN</td><td rowspan="2">Palmetto GBA does not require notification for CMS approvals.

As of June 5, 2019, Palmetto GBA <u>no longer requires</u> individual notifications for IDEs that have been nationally approved by CMS.</td><td rowspan="2">Billing Instructions for Investigational Device Exemptions (IDEs):
http://www.palmettogba.com
Select Part A or Part B under your jurisdiction. (Search for… “Investigational”)</td></tr>
<tr><td>Palmetto (J-M)</td><td>NC, SC, VA, WV</td></tr>
</table>

U.S. Map of CMS Part A/B Medicare Administrative Contractors (A/B MACs)



Note: As of September 2020, there are four A/B MAC jurisdictions that do NOT require sites to submit a *Notification of IDE Study Participation* for central CMS-approved studies. These include:

1. **Palmetto JJ** (AL, GA, TN)
2. **Palmetto JM** (NC, SC, VA, WV)
3. **WPS GHA J5** (IA, KS, MO, NE)*
4. **WPS GHA J8** (IN, MI)

**Including Part A Medicare benefit administration for J5 National providers*

For assistance regarding the A/B MAC Notification Process – Email your questions to payments@conformalmedical.com.

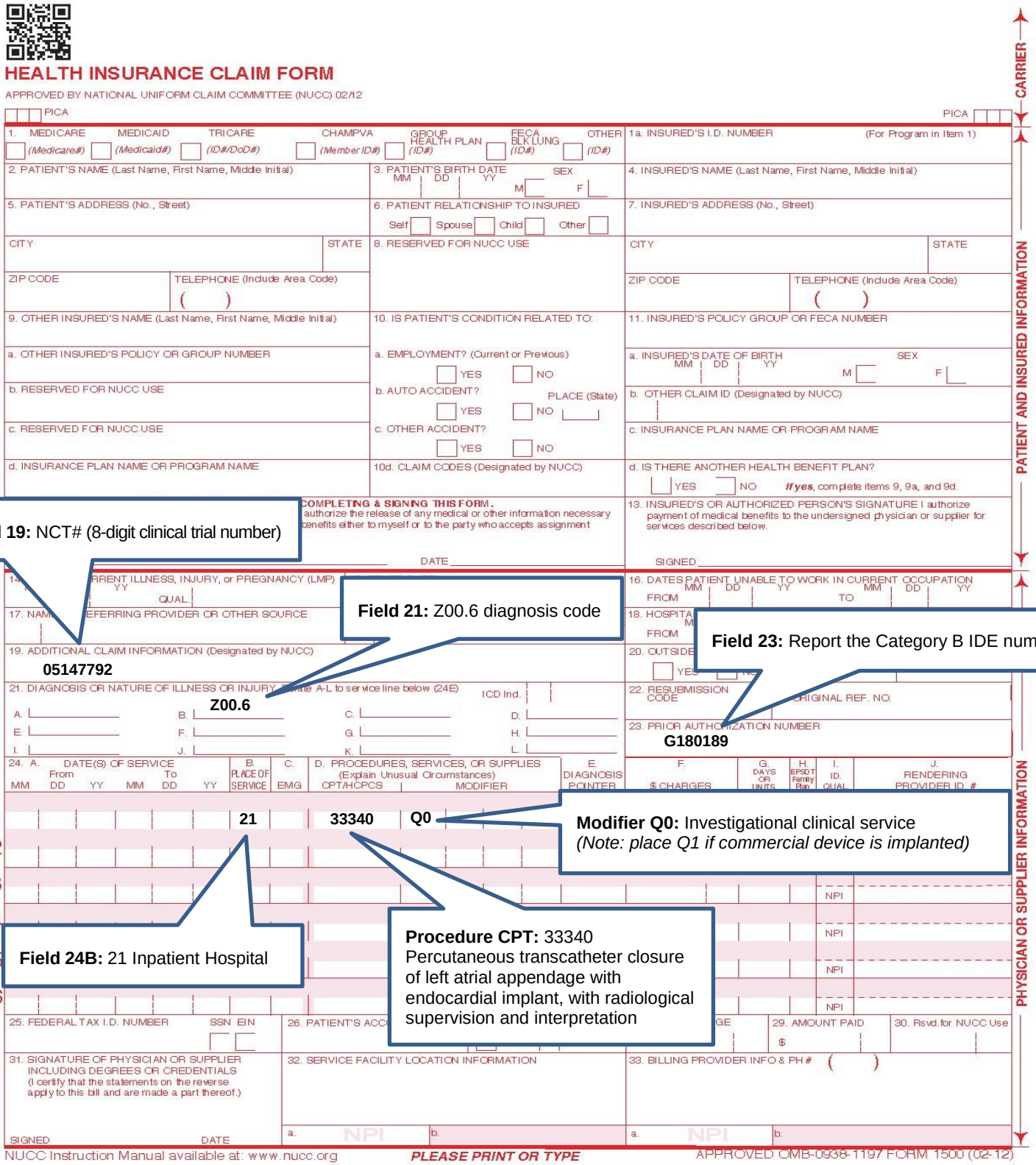
APPENDIX B: COMMONLY USED BILLING CODES

Commonly Billed Procedure Codes for LAAC Device Therapy

	Code	Description
Physician	**33340**	*Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation*
Physician	**93312**	*Echocardiography, transesophageal, real-time with image documentation (2D) (with or without M-mode recording); including probe placement, image acquisition, interpretation and report* **Note:** CPT code 93312 is used by physicians to report baseline and follow-up TEE
Physician	**93355**	*Echocardiography, transesophageal (TEE) for guidance of a transcatheter intracardiac or great vessel(s) structural intervention(s) (eg,TAVR, transcathether pulmonary valve replacement, mitral valve repair, paravalvular regurgitation repair, left atrial appendage occlusion/closure, ventricular septal defect closure) (peri-and intra-procedural), real-time image acquisition and documentation, guidance with quantitative measurements, probe manipulation, interpretation, and report, including diagnostic transesophageal echocardiography and, when performed, administration of ultrasound contrast, Doppler, color flow, and 3D* **Note:** CPT code 93355 is used by physicians to report Intraoperative TEE. CPT code 93355 is reported once per intervention and only by an individual who is NOT performing the interventional procedure (i.e., CLAAS implant). *If two or more procedures that require the use of an unlisted code are performed on different anatomic locations the unlisted code may be reported for each different anatomic location. *CPT Assistant*, April 2012
Inpatient Hospital	**02L73DK**	*Occlusion of Left Atrial Appendage with Intraluminal Device, Percutaneous Approach* **Note:** ICD-10-PCS code 02L73DK is used by hospitals to report the CLAAS device implant procedure in the inpatient setting. The LAAC procedure is designated by Medicare as “inpatient only” (APC Status Indicator “C”). There is no HCPCS product category “C-code” assigned to the CLAAS Device.
	DRG	MS-DRG 273 or MS-DRG 274
	Diagnosis Codes	I48.91 Unspecified Atrial Fibrillation I48.20 Chronic Atrial Fibrillation, Unspecified I48.21 Permanent Atrial Fibrillation I48.0 Paroxysmal Atrial Fibrillation I48.11 Longstanding Persistent Atrial Fibrillation I48.19 Other Persistent Atrial Fibrillation

Notice: The above codes are for example and discussion only. Fewer, additional or other codes than those listed may apply. With any new technology, it is important to query your payers and certified coding specialists for guidance.

APPENDIX C: MEDICARE CLAIM FORM EXAMPLES



HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA

1. MEDICARE (Medicare#) MEDICAID (Medicaid#) TRICARE (ID#/DoD#) CHAMPVA (Member ID#) GROUP HEALTH PLAN (ID#) FECA BLK LUNG (ID#) OTHER (ID#)

1a. INSURED'S I.D. NUMBER (For Program in Item 1)

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE MM DD YY SEX M F

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED Self Spouse Child Other

7. INSURED'S ADDRESS (No., Street)

CITY STATE

8. RESERVED FOR NUCC USE

CITY STATE

ZIP CODE TELEPHONE (Include Area Code)

ZIP CODE TELEPHONE (Include Area Code)

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

a. OTHER INSURED'S POLICY OR GROUP NUMBER

a. EMPLOYMENT? (Current or Previous) YES NO

a. INSURED'S DATE OF BIRTH MM DD YY SEX M F

b. RESERVED FOR NUCC USE

b. AUTO ACCIDENT? PLACE (State) YES NO

b. OTHER CLAIM ID (Designated by NUCC)

c. RESERVED FOR NUCC USE

c. OTHER ACCIDENT? YES NO

c. INSURANCE PLAN NAME OR PROGRAM NAME

d. INSURANCE PLAN NAME OR PROGRAM NAME

10d. CLAIM CODES (Designated by NUCC)

d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO *If yes*, complete items 9, 9a, and 9d.

COMPLETING & SIGNING THIS FORM. authorize the release of any medical or other information necessary benefits either to myself or to the party who accepts assignment

DATE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED

14. RRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY QUAL.

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION MM DD YY TO MM DD YY

17. NAM EFERRING PROVIDER OR OTHER SOURCE

18. HOSPITA FROM

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

05147792

20. OUTSIDE YES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Relate A-L to service line below (24E) ICD Ind.

Z00.6

A. B. C. D. E. F. G. H. I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

G180189

24. A. DATE(S) OF SERVICE From MM DD YY To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL	J. RENDERING PROVIDER ID. #
1	21		33340	Q0						NPI
2										NPI
3										NPI
4										NPI
5										
6										

25. FEDERAL TAX I.D. NUMBER SSN EIN

26. PATIENT'S ACC GE

29. AMOUNT PAID $

30. Rsvd.for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED DATE

32. SERVICE FACILITY LOCATION INFORMATION

a. NPI b.

33. BILLING PROVIDER INFO & PH # ( )

a. NPI b.

CARRIER

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

APPROVED OMB-0938-1197 FORM 1500 (02-12)

Field 19: NCT# (8-digit clinical trial number)

Field 21: Z00.6 diagnosis code

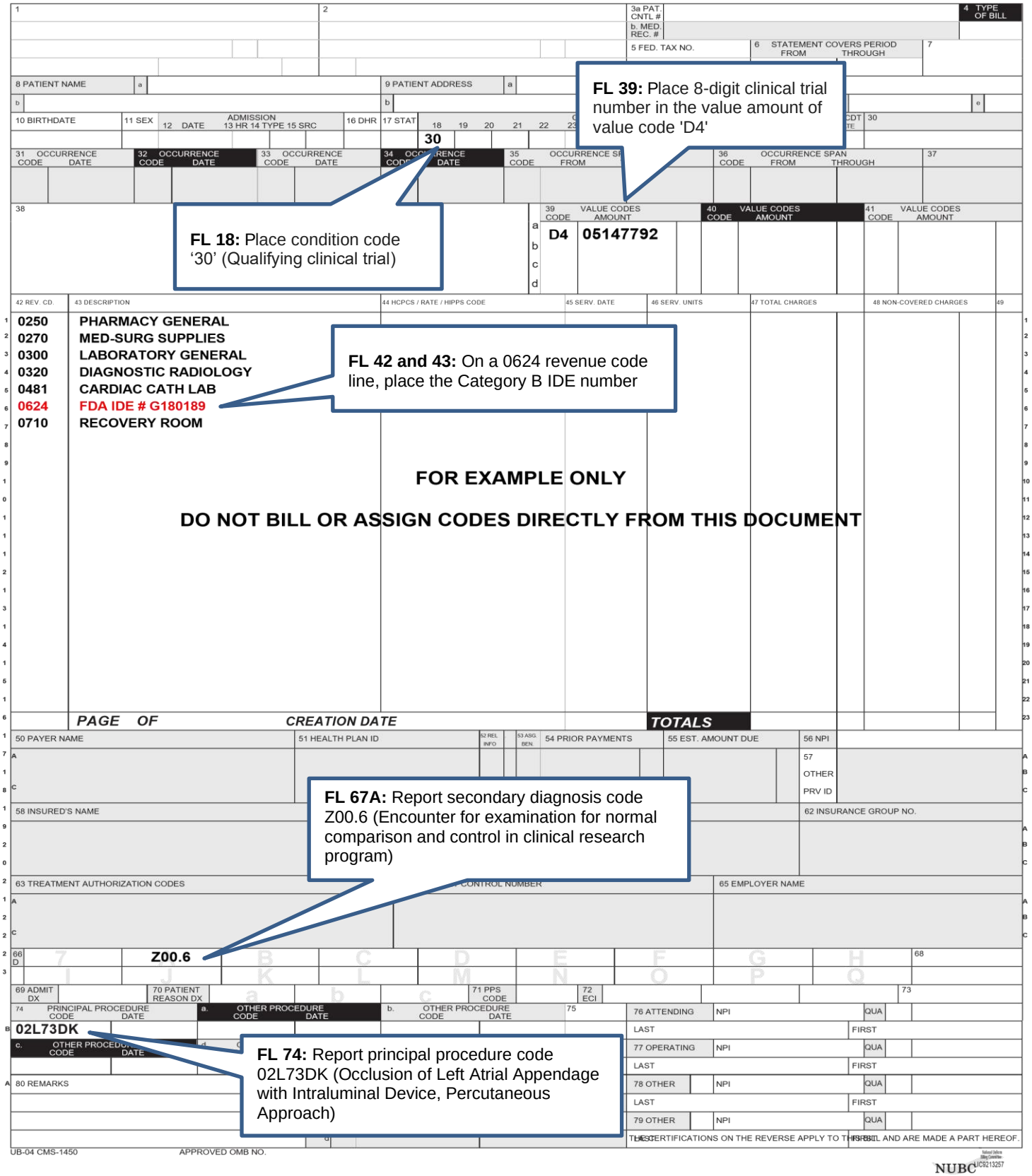
Field 23: Report the Category B IDE number

Modifier Q0: Investigational clinical service
(Note: place Q1 if commercial device is implanted)

Field 24B: 21 Inpatient Hospital

Procedure CPT: 33340
Percutaneous transcatheter closure of left atrial appendage with endocardial implant, with radiological supervision and interpretation

APPENDIX C: MEDICARE CLAIM FORM EXAMPLES



APPENDIX D: SAMPLE PRIOR AUTHORIZATION LETTER

SAMPLE PRIOR AUTHORIZATION LETTER FOR THE CLAAS DEVICE SYSTEM

NOTE TO PHYSICIAN INVESTIGATOR: This sample letter is not meant to be used as a form letter. You should customize the letter to reflect the particular background, medical history and diagnosis of the specific patient, as well as any special requirements of the payer involved. You are responsible for providing true, accurate and complete information concerning the applicable diagnosis and procedure codes and the patient's medical record, and ensuring the medical necessity of the procedure.

This letter is intended as an example for your consideration and may not include all the information necessary to support your prior authorization request. The requesting facility is entirely responsible for ensuring the accuracy, adequacy, and supportability of all information provided. As a reminder, Medicare does not preauthorize medical procedures. It is recommended that you contact your patient's insurance company to obtain specific inclusion/exclusion criteria.

Health economic and reimbursement information provided by Conformal Medical is gathered from third-party sources and is subject to change without notice as a result of complex and frequently changing laws, regulations, rules and policies. This information is presented for illustrative purposes only and does not constitute reimbursement or legal advice. Conformal Medical encourages providers to submit accurate and appropriate claims for services. It is always the provider's responsibility to determine medical necessity, the proper site for delivery of any services and to submit appropriate codes, charges, and modifiers for services that are rendered. Conformal Medical recommends that you consult with your payers, reimbursement specialists and/or legal counsel regarding coding, coverage and reimbursement matters.

Payer policies will vary and should be verified prior to treatment for limitations on diagnosis, coding or site of service requirements. The coding options listed within this guide are commonly used codes and are not intended to be an all-inclusive list. Providers are responsible for making appropriate decisions related to coding and reimbursement submissions.

Instructions for completing the sample prior authorization letter:

1. Sections which require customization are **highlighted in yellow**. Edit these sections to reflect medical appropriateness of the CLAAS Device for the individual patient.

2. It is important to provide the most complete information to assist with the appeals process.

3. Delete the highlighted instructions for completion, so the health plan does not misinterpret the resulting submission as a form letter.

4. Questions may be directed to payments@conformalmedical.com.

[Date]

Attention: Surgery Preauthorization Department
[Insurance Company address]

RE: Patient Name: _____
Policy Holder Name: _____
Patient ID #: _____
Policy, Group, or Claim # _____

Requested for procedure: CPT code: 33340 and ICD-10 PCS procedure code: 02L73DK provided within the context of CONFORM IDE clinical study participation.

Dear Madam/Sir:

This letter is to request approval for the surgery, hospital, and post-surgical care associated with the planned implantation of either the CLAAS Left Atrial Appendage closure (LAAC) System or a commercially available Left Atrial Appendage Occlusion (LAAO) device for [patient name]. This patient is scheduled for surgery on [insert date]. I have attached the clinical documentation (i.e. history and physical, and operative reports) to support medical necessity for LAAC candidacy.

These services will be provided within the context of this patient's participation in the *CONFORM* Pivotal Trial titled An Evaluation of the Safety and Effectiveness of the Conformal CLAAS System for Left Atrial Appendage Occlusion. The CONFORM Pivotal Trial is registered with the National Institutes of Health (NIH) National Library of Medicine's (NLM) ClinicalTrials.gov at: https://clinicaltrials.gov/ct2/show/NCT05147792.

LAAC Therapy

AF is associated with a substantially increased risk of stroke and thromboembolic events,[2] primarily due to the Left Atrial Appendage (LAA) serving as a site for thrombus formation. Echocardiographic evidence that the LAA is the source of thrombi in more than 90% of patients with AF has prompted the development of novel transcatheter therapies to occlude the LAA, thereby excluding it from the circulation in AF patients with non-valvular AF.[3,4,5,6,7] The WATCHMAN® Left Atrial Appendage Closure Device (Boston Scientific Corporation) was the first Left Atrial Appendage Occlusion (LAAO) device extensively clinically evaluated. Randomized clinical trials have shown the WATCHMAN to have acceptable benefit to risk ratios for LAA closure in patients with non-valvular AF and a high risk for stroke or systemic embolism

[2] Wolf PA, Abbott RD and Kannel WB. Atrial fibrillation as an independent risk factor for stroke: the Framingham Study. *Stroke*. 1991;22:983-8
[3] Goldman ME, Pearce LA, Hart RG, et al. Pathophysiologic correlates of thromboembolism in nonvalvular atrial fibrillation: I. Reduced flow velocity in the left atrial appendage (The Stroke Prevention in Atrial Fibrillation [SPAF-III] study). *J Am Soc Echocardiogr*. 1999;12:1080-7.
[4] Blackshear JL and Odell JA. Appendage obliteration to reduce stroke in cardiac surgical patients with atrial fibrillation. *Ann Thorac Surg*. 1996;61:755-9.
[5] Bayard YL, Omran H, Neuzil P, et al. PLAATO (Percutaneous Left Atrial Appendage Transcatheter Occlusion) for prevention of cardioembolic stroke in non-anticoagulation eligible atrial fibrillation patients: results from the European PLAATO study. *EuroIntervention*. 2010;6:220-6.
[6] Ostermayer SH, Reisman M, Kramer PH, et al. Percutaneous left atrial appendage transcatheter occlusion (PLAATO system) to prevent stroke in high-risk patients with non-rheumatic atrial fibrillation: results from the international multi-center feasibility trials. *J Am Coll Cardiol*. 2005;46:9-14.
[7] Sievert H, Lesh MD, Trepels T, et al. Percutaneous left atrial appendage transcatheter occlusion to prevent stroke in high-risk patients with atrial fibrillation: early clinical experience. *Circulation*. 2002;105:1887-9.

and an appropriate rationale to seek a non-pharmacologic alternative to oral anticoagulation.[8,9] The WATCHMAN device received FDA approval in March 2015. While LAA closure with the WATCHMAN and Amplatzer devices represents an important advance in stroke prevention for patients with AF, important limitations and opportunities for improvement exist, including a technically challenging implantation procedure, restrictions of the LAA anatomies that can be effectively sealed, and low but persistent rates of residual leaks and device-related thrombus. Conformal Medical, Inc., the study sponsor, has developed the CLAAS Device to address these limitations of the first generation LAAO device.

Intended Use

The CLAAS system is intended to reduce the risk of thromboembolism from the left atrial appendage in patients with non-valvular atrial fibrillation who:

- Are at increased risk for stroke and systemic embolism based on CHADS2 or CHA2DS2-VASc scores and are recommended for oral anticoagulation (OAC) therapy; AND
- Are deemed by their physician to be suitable for OAC; AND
- Have an appropriate rationale to seek a non-pharmacological alternative to OAC, taking into account the safety and effectiveness of the device compared to OAC.

CLAAS System Therapy

The CLAAS® System delivers a plug to the ostia of the Left Atrial Appendage (LAA) and is designed to occlude the appendage to eliminate blood flow. The Implant is pre-attached to the Delivery Catheter and loaded by the user into the Delivery Catheter at the time of the procedure. The Delivery System consists of:

1) CLAAS Delivery Catheter with Implant and Loading Cone,
2) Access Sheath with Dilator;

The system is designed to track through the vascular anatomy from the femoral vein to the LAA. The system includes an Access Sheath with Dilator to accommodate vascular access using a standard femoral vein approach to the right atrium, across the atrial septum, and into the LAA. Echocardiography and fluoroscopy are used during the procedure to verify sizing and to aid in deployment of the Implant to the target location.

CONFORM IDE Study Rationale and Design

The CLAAS system is designed to provide the benefits of left atrial appendage closure with a conventional device, while potentially simplifying the implantation procedure, improving procedural safety, and reducing peri-device leakage. The study will evaluate the safety and effectiveness of LAA closure with the CLAAS system in patients with non-valvular atrial fibrillation who are at increased risk for stroke and systemic embolism.

This is a pivotal clinical trial that includes three components: (1) a Roll-In Phase using the CLAAS system alone (up to 3 subjects per investigational site), (2) a Randomized Clinical Trial (RCT) comparing CLAAS to commercially available LAAO systems (up to 1600 subjects), and

[8] Holmes DR, Reddy VY, Turi ZG, et al. Percutaneous closure of the left atrial appendage versus warfarin therapy for prevention of stroke in patients with atrial fibrillation: a randomised non-inferiority trial. *Lancet*. 2009;374:534-42.
[9] Holmes DR, Jr., Kar S, Price MJ, et al. Prospective randomized evaluation of the Watchman Left Atrial Appendage Closure device in patients with atrial fibrillation versus long-term warfarin therapy: the PREVAIL trial. *J Am Coll Cardiol*. 2014;64:1-12.

(3) a subsequent, single arm sub-study investigating the use of conscious sedation; conducted after enrollment in the RCT is complete (130 subjects).

The study will be executed as a staged trail with a clinical safety summary of the initial 50 CLAAS implanted subjects to confirm safety prior to advancing to the second stage. The study will be limited to 250 total US subjects during this initial stage. The second stage will be initiated after receiving confirmation from FDA to continue after they have reviewed the safety summary.

The control devices for the study will be any commercially available transcatheter LAAO devices. All three FDA approved LAAO devices (Boston Scientific WATCHMAN device, WATCHMAN FLX and Abbott Laboratories, Amulet device) can be used in subjects assigned to the Control Group.

The control devices will be placed in accordance with the approved Instructions for Use and all subjects will be managed through the same follow-up timeframe as the treatment device in accordance with the FDA approved labeling for post procedure anticoagulation/antiplatelet medication.

The trial is anticipated to take approximately 8 years to complete. Each subject will be followed for 5 years. Follow-up visits may occur as part of an expanded access and/or post-approval study, should the CLAAS device gain approval for commercial distribution prior to the subject's 5-year visit.

CMS National Coverage Determination (NCD) established for Percutaneous LAAC Therapy

CMS issued a Medicare National Coverage Determination (NCD) on February 8, 2016 which allows for coverage of LAAC under Coverage with Evidence Development (CED) with certain conditions. To access the NCD for percutaneous LAAC therapy in its entirety, please click here. The CONFORM Pivotal Trial is a Medicare-Approval clinical trial under CMS' criteria for CED as set forth within the NCD for LAAC. CED is a paradigm whereby Medicare covers items and services on the condition that they are furnished in the context of approved clinical studies or with the collection of additional clinical data. In making coverage decisions involving CED, CMS decides after a formal review of the medical literature to cover an item or service only in the context of an approved clinical study or when additional clinical data are collected to assess the appropriateness of an item or service for use with a particular beneficiary.[10]

The CONFORM Pivotal Trial has been reviewed by the CMS' national office and was approved for Medicare coverage on **March 23, 2022** after a thorough review by CMS staff under their strict CED standards of scientific integrity criteria as set forth within the NCD for LAAC. Approval of the CONFORM Pivotal Trial can be found at the following CMS webpage:
https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/LAAC

Because your health plan either has no coverage criteria or non-covers percutaneous LAAC therapy, I am specifically requesting prior authorization for this procedure based on my patient meeting the NCD for LAAC as referenced.

[10] Centers for Medicare and Medicaid Services (CMS): Guidance for the Public, Industry, and CMS Staff: *Coverage with Evidence Development* (11/20/2014), available at: https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27

Patient Medical Appropriateness for LAAC
I have discussed the procedure with my patient and they have made the decision to have an LAAO device implanted.

[Physician to insert any additional comments supporting why they and their patient have chosen this procedure as an alternative to warfarin therapy. Reference supporting medical documentation.]

I feel that ***(patient name)*** will benefit greatly from this procedure. **(*Her/His)*** quality of life and well-being is greatly impacted by atrial fibrillation. In addition to atrial fibrillation, ***(patient)*** also suffers from ***(list all other health-related conditions that patient suffers from and include diagnoses that apply. Provide a brief description of patient's therapies, including medical management, to date.)***

The patient's current medical management regimen includes: [_____].
Side effects suffered from these medications include: [_____].
[*Include patient's $CHADS_2$ or CHA_2DS_2 VASc Scores in terms of likelihood for embolic stroke]*

In addition, the heart team agrees that ***(patient)*** has an on-label United States Food and Drug Administration (FDA) approved indication for LAAC is appropriate. It's important to note that my patient is indicated for LAAC therapy regardless of their participation within the CONFORM Pivotal Trial.

Coding
The LAAC procedure is reported with CPT code **33340** Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation.
[Include CPT codes (93312-93320, or 93325 or 93355) for performing transesophageal echocardiography (TEE) if applicable.]
The relevant ICD10-PCS code for inpatient hospital reporting of the procedure is **02L73DK**: Occlusion of left atrial appendage with intraluminal device, percutaneous approach. Medicare has restricted this procedure to the inpatient hospital site of service. I would like to request prior authorization for these anticipate procedure codes.
My patient, [**Patient name**] is medically appropriate for this procedure, and we request that approval be granted for surgery and all related services as soon as possible. Please fax your approval to my office at the following number [**fax number**] or contact me with additional questions. I can be reached conveniently at [**telephone number**].
Sincerely,
[Physician Name]
[Practice Name]

APPENDIX E: SAMPLE APPEAL LETTER

SAMPLE APPEAL LETTER FOR THE CLAAS DEVICE SYSTEM

PLEASE NOTE: This letter is intended as an example for your consideration and may not include all the information necessary to support your appeal request. The requesting facility is entirely responsible for ensuring the accuracy, adequacy, and supportability of the information provided. You are responsible for providing true, accurate and complete information concerning the applicable diagnosis and procedure codes and the patient's medical record, and ensuring the medical necessity of the procedure.

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Payer policies will vary and should be verified prior to treatment for limitations on diagnosis, coding or site of service requirements. The coding options listed within this guide are commonly used codes and are not intended to be an all-inclusive list. Providers are responsible for making appropriate decisions related to coding and reimbursement submissions.

Instructions for completing the sample appeal letter:

5. Sections which require customization are **highlighted in yellow**. Edit these sections to reflect medical appropriateness of the CLAAS Device for the individual patient.

6. It is important to provide the most complete information to assist with the appeals process.

7. Delete the highlighted instructions for completion, so the health plan does not misinterpret the resulting submission as a form letter.

8. Questions may be directed to payments@conformalmedical.com.

[Date]

Attention: Appeals Department
Reference number: [ ]
[Insurance Company name]
[Insurance Company address]
[Fax:]

RE: Patient Name: _____
Policy Holder Name: _____
Patient ID #: _____
Policy, Group, or Claim # _____

Principal Diagnosis: [**list ICD10 diagnosis code and diagnosis code descriptor**]
Procedure/Service: [Physician report with **33340** Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement, left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation **OR** Inpatient Hospital report with **02L73DK**: Occlusion of left atrial appendage with intraluminal device, percutaneous approach]

RE: Request for Coverage Reconsideration for Left Atrial Appendage Closure (LAAC) within the context of CONFORM clinical study participation

To Whom It May Concern:

I am contacting you on behalf of my patient, ***(name)*** to appeal a prior denial received on ***(date)*** for the percutaneous insertion of a left atrial appendage closure device to reduce his/her risk of stroke as a result of his/her non-valvular atrial fibrillation. This letter documents the medical necessity for this therapy and provides information about the patient's medical history and treatment, as supporting clinical rationale for the device and procedure.

These services will also be provided within the context of this patient's participation in the *CONFORM* Pivotal Trial titled An Evaluation of the Safety and Effectiveness of the Conformal CLAAS System for Left Atrial Appendage Occlusion. The CONFORM Pivotal Trial is registered with the National Institutes of Health (NIH) National Library of Medicine's (NLM) ClinicalTrials.gov at: https://clinicaltrials.gov/ct2/show/NCT05147792.

Background and Historical Treatment

Atrial fibrillation (AF) is the most common clinically significant cardiac tachyarrhythmia, affecting more than 33 million patients worldwide, with a projected incidence of 5 million patients per year.[11] In the United States alone, approximately 6 million individuals suffer from AF and over one million new cases are diagnosed annually; due to the aging population, the number is expected to double by the year 2030.[12,13]

[11] Chugh SS, Havmoeller R, Narayanan K, et al. Worldwide epidemiology of atrial fibrillation: a Global Burden of Disease 2010 Study. Circulation. 2014;129:837-47.
[12] Colilla S, Crow A, Petkun W, et al. Estimates of current and future incidence and prevalence of atrial fibrillation in the U.S. adult population. Am J Cardiol. 2013;112:1142-7.
[13] Go AS, Hylek EM, Phillips KA, et al. Prevalence of diagnosed atrial fibrillation in adults: national implications for rhythm management and stroke prevention: the AnTicoagulation and Risk Factors in Atrial Fibrillation (ATRIA) Study. JAMA. 2001;285:2370-5.

AF is associated with a substantially increased risk of stroke and thromboembolic events,[14] primarily due to the Left Atrial Appendage (LAA) serving as a site for thrombus formation. Untreated patients with AF have a 2-5% annual incidence of stroke, with a history of stroke or thromboembolic events conferring an even higher risk.[15,16] Strokes that occur with AF are large and can be quite debilitating, leading to death or costly and painful rehabilitation and adding significant financial burden to the medical system.

The standard treatment for stroke prevention in subjects with AF is oral anticoagulant (OAC) therapy to reduce the likelihood of clot formation, which is recommended regardless of the management strategy of the underlying rhythm disorder.[17] While pharmacotherapy can reduce stroke incidence in AF by approximately 60%,[18] OAC therapy is associated with an increased risk of bleeding complications,[19] an issue of significant concern due to the high bleeding risk of many AF patients. In addition, management of OAC therapy is burdensome and long-term compliance is poor, leaving patients at risk for embolic events.

Echocardiographic evidence that the LAA is the source of thrombi in more than 90% of patients with AF has prompted the development of novel transcatheter therapies to occlude the LAA, thereby excluding it from the circulation in AF patients with non-valvular AF.[20,21,22,23,24] The WATCHMAN® Left Atrial Appendage Closure Device (Boston Scientific Corporation) was the first Left Atrial Appendage Occlusion (LAAO) device extensively clinically evaluated. Randomized clinical trials have shown the WATCHMAN to have acceptable benefit to risk ratios for LAA closure in patients with non-valvular AF and a high risk for stroke or systemic embolism and an appropriate rationale to seek a non-pharmacologic alternative to oral anticoagulation.[25,26] The WATCHMAN device received FDA approval in March 2015.

A second-generation WATCHMAN Device, WATCHMAN FLX™ was developed to simplify LAAO. WATCHMAN FLX received FDA approval in July 2020. Recently, Abbott Laboratories received FDA Approval for the Amplatzer Amulet Left Atrial Appendage Occluder.

---

[14] Wolf PA, Abbott RD and Kannel WB. Atrial fibrillation as an independent risk factor for stroke: the Framingham Study. *Stroke*. 1991;22:983-8.

[15] Mennuni M, Penzo C, Ferrante G, et al. Percutaneous Left Atrial Appendage Closure: Rational, Patient Selection, and Preoperative Evaluation. In: B. Reimers, I. Moussa and A. Pacchioni, eds. *Percutaneous Interventions for Structural Heart Disease: An Illustrated Guide* Cham: Springer International Publishing; 2017: 191-198.

[16] Peritz DC and Chung EH. Left atrial appendage closure: An emerging option in atrial fibrillation when oral anticoagulants are not tolerated. *Cleve Clin J Med*. 2015;82:167-76.

[17] Holmes DR, Reddy VY, Turi ZG, et al. Percutaneous closure of the left atrial appendage versus warfarin therapy for prevention of stroke in patients with atrial fibrillation: a randomised non-inferiority trial. *Lancet*. 2009;374:534-42.

[18] Hart RG, Benavente O, McBride R, et al. Antithrombotic therapy to prevent stroke in patients with atrial fibrillation: a meta-analysis. *Ann Intern Med*. 1999;131:492-501.

[19] Gage BF, Boechler M, Doggette AL, et al. Adverse outcomes and predictors of underuse of antithrombotic therapy in medicare beneficiaries with chronic atrial fibrillation. *Stroke*. 2000;31:822-7.

[20] Goldman ME, Pearce LA, Hart RG, et al. Pathophysiologic correlates of thromboembolism in nonvalvular atrial fibrillation: I. Reduced flow velocity in the left atrial appendage (The Stroke Prevention in Atrial Fibrillation [SPAF-III] study). *J Am Soc Echocardiogr*. 1999;12:1080-7.

[21] Blackshear JL and Odell JA. Appendage obliteration to reduce stroke in cardiac surgical patients with atrial fibrillation. *Ann Thorac Surg*. 1996;61:755-9.

[22] Bayard YL, Omran H, Neuzil P, et al. PLAATO (Percutaneous Left Atrial Appendage Transcatheter Occlusion) for prevention of cardioembolic stroke in non-anticoagulation eligible atrial fibrillation patients: results from the European PLAATO study. *EuroIntervention*. 2010;6:220-6.

[23] Ostermayer SH, Reisman M, Kramer PH, et al. Percutaneous left atrial appendage transcatheter occlusion (PLAATO system) to prevent stroke in high-risk patients with non-rheumatic atrial fibrillation: results from the international multi-center feasibility trials. *J Am Coll Cardiol*. 2005;46:9-14.

[24] Sievert H, Lesh MD, Trepels T, et al. Percutaneous left atrial appendage transcatheter occlusion to prevent stroke in high-risk patients with atrial fibrillation: early clinical experience. *Circulation*. 2002;105:1887-9.

[25] Holmes DR, Reddy VY, Turi ZG, et al. Percutaneous closure of the left atrial appendage versus warfarin therapy for prevention of stroke in patients with atrial fibrillation: a randomised non-inferiority trial. *Lancet*. 2009;374:534-42.

[26] Holmes DR, Jr., Kar S, Price MJ, et al. Prospective randomized evaluation of the Watchman Left Atrial Appendage Closure device in patients with atrial fibrillation versus long-term warfarin therapy: the PREVAIL trial. *J Am Coll Cardiol*. 2014;64:1-12.

While LAA closure with the WATCHMAN and Amplatzer devices represents an important advance in stroke prevention for patients with AF, important limitations and opportunities for improvement exist, including a technically challenging implantation procedure, restrictions of the LAA anatomies that can be effectively sealed, and low but persistent rates of residual leaks and device-related thrombus.

2019 AHA/ACC/HRS Guideline for the Management of Patients with Atrial Fibrillation

The 2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients with Atrial Fibrillation recommends Percutaneous LAAO therapy as a **Class IIb therapy and LOE B-NR**. The guidelines state that Percutaneous LAA occlusion may be considered in patients with AF at increased risk of stroke who have contraindications to long-term anticoagulation.

The CLAAS Device

The CLAAS® System delivers a plug to the ostia of the Left Atrial Appendage (LAA) and is designed to occlude the appendage to eliminate blood flow. The Implant is pre-attached to the Delivery Catheter and loaded by the user into the Delivery Catheter at the time of the procedure. The Delivery System consists of:

1) CLAAS Delivery Catheter with Implant and Loading Cone,
2) Access Sheath with Dilator

The system is designed to track through the vascular anatomy from the femoral vein to the LAA. The system includes an Access Sheath with Dilator to accommodate vascular access using a standard femoral vein approach to the right atrium, across the atrial septum, and into the LAA. Echocardiography and fluoroscopy are used during the procedure to verify sizing and to aid in deployment of the Implant to the target location.

Intended Use

The CLAAS system is intended to reduce the risk of thromboembolism from the left atrial appendage in patients with non-valvular atrial fibrillation who:

- Are at increased risk for stroke and systemic embolism based on CHADS2 or CHA2DS2-VASc scores and are recommended for oral anticoagulation (OAC) therapy; AND
- Are deemed by their physician to be suitable for OAC; AND
- Have an appropriate rationale to seek a non-pharmacological alternative to OAC, taking into account the safety and effectiveness of the device compared to OAC.

CONFORM Pivotal Trial Rationale

The CLAAS system is designed to provide the benefits of left atrial appendage closure with a conventional device, while potentially simplifying the implantation procedure, improving procedural safety, and reducing the peri-device leakage. The study will evaluate the safety and effectiveness of LAA closure with the CLAAS system in patients with non-valvular atrial fibrillation who are at increased risk for stroke and systemic embolism.

This is a pivotal clinical trial that includes three components: (1) a Roll-In Phase using the CLAAS system alone (up to 3 subjects per investigational site), (2) a Randomized Clinical Trial (RCT) comparing CLAAS to commercially available LAAO systems (up to 1600 subjects), and (3) a subsequent, single arm sub-study investigating the use of conscious sedation; conducted after

enrollment in the RCT is complete (130 subjects).

The study will be executed as a staged trail with a clinical safety summary of the initial 50 CLAAS implanted subjects to confirm safety prior to advancing to the second stage. The study will be limited to 250 total US subjects during this initial stage. The second stage will be initiated after receiving confirmation from FDA to continue after they have reviewed the safety summary.

The trial is anticipated to take approximately 8 years to complete. Each subject will be followed for 5 years. Follow-up visits may occur as part of an expanded access and/or post-approval study, should the CLAAS device gain approval for commercial distribution prior to the subject's 5-year visit.

CMS National Coverage Determination (NCD) established for Percutaneous LAAC Therapy

CMS issued a Medicare National Coverage Determination (NCD) on February 8, 2016 which allows for coverage of LAAC under Coverage with Evidence Development (CED) with certain conditions. To access the NCD for percutaneous LAAC therapy in its entirety, please click here.

The CONFORM Pivotal Trial is a Medicare-Approval clinical trial under CMS' criteria for CED as set forth within the NCD for LAAC. CED is a paradigm whereby Medicare covers items and services on the condition that they are furnished in the context of approved clinical studies or with the collection of additional clinical data. In making coverage decisions involving CED, CMS decides after a formal review of the medical literature to cover an item or service only in the context of an approved clinical study or when additional clinical data are collected to assess the appropriateness of an item or service for use with a particular beneficiary.[27]

The CONFORM Pivotal Trial has been reviewed by the CMS' national office and was approved for Medicare coverage on **March 23, 2022** after a thorough review by CMS staff under their strict CED standards of scientific integrity criteria as set forth within the NCD for LAAC. Approval of the CONFORM Pivotal Trial can be found at the following CMS webpage: https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/LAAC

Patient Medical necessity for LAAC

I have discussed the procedure with my patient, ***(name)***, in assessing the benefits and risks of this therapy and my patient has made the decision to have an LAAO device implanted.

[Physician to insert any additional comments supporting why they and their patient have chosen this procedure]

I feel that ***(patient name)*** will benefit greatly from this procedure. (***Her/His)*** quality of life and well-being is greatly impacted by atrial fibrillation. In addition to atrial fibrillation, ***(patient)*** also suffers from ***(list all other health-related conditions that patient suffers from and include diagnoses that apply. Provide a brief description of patient's therapies, including medical management, to date)***.

The patient's current medical management regimen includes:[ ].
Side effects suffered from these medications include:[ ].
[*Include patient's CHADS$_2$ or CHA$_2$DS$_2$ VASc Scores in terms of likelihood for embolic stroke*]

[27] Centers for Medicare and Medicaid Services (CMS): Guidance for the Public, Industry, and CMS Staff: Coverage with Evidence Development (11/20/2014), available at: https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27

[*Include the following if you determine to be applicable:]*
Over the last decade, accessing the heart via a left heart catheterization is becoming a fairly routine procedure due to an increase in percutaneous techniques for mitral valvuloplasties, atrial septal defect and patent foramen ovale closure procedures. In my practice, I have performed well over ***(number)*** of these left heart catheterization procedures, including ***(number)*** of LAAO implants. The insertion of this left atrial appendage closure device is a catheter-based procedure performed in the catheterization or EP laboratory during a left heart catheterization.

I am specifically requesting health plan reconsideration of the prior denial of coverage for this procedure based on my patient's documented medical necessity for this therapy.

If you have any further questions or require additional information, please feel free to contact me at (***physician's telephone number).*** Thank you in advance for your immediate attention to this request.

Sincerely,

[Physician's name]
[Practice name]