**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.

1. 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,[[1]](#footnote-1) 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.[[2]](#footnote-2),[[3]](#footnote-3),[[4]](#footnote-4),[[5]](#footnote-5),[[6]](#footnote-6) 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.[[7]](#footnote-7),[[8]](#footnote-8) 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 (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](https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=281).

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.[[9]](#footnote-9)

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.**

**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 CHADS2 or CHA2DS2 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]**

1. Wolf PA, Abbott RD and Kannel WB. Atrial fibrillation as an independent risk factor for stroke: the Framingham Study. *Stroke*. 1991;22:983-8 [↑](#footnote-ref-1)
2. 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. [↑](#footnote-ref-2)
3. Blackshear JL and Odell JA. Appendage obliteration to reduce stroke in cardiac surgical patients with atrial fibrillation. *Ann Thorac Surg*. 1996;61:755-9. [↑](#footnote-ref-3)
4. 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. [↑](#footnote-ref-4)
5. 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. [↑](#footnote-ref-5)
6. 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. [↑](#footnote-ref-6)
7. 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. [↑](#footnote-ref-7)
8. 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. [↑](#footnote-ref-8)
9. 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> [↑](#footnote-ref-9)