**SAMPLE APPEAL LETTER FOR THE WATCHMAN™ LEFT ATRIAL APPENDAGE CLOSURE (LAAC) PROCEDURE**

**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.

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**Instructions for completing the sample appeal letter:**

1. Please customize the appeals template based on the medical appropriateness of the WATCHMAN™ Device for your patient. Fields required for customization are **highlighted in yellow**.
2. It is important to provide the most complete information to assist with the appeals process.
3. After you have customized the appeals letter, please make sure to delete any specific instructions for completion that are highlighted throughout the letter so the health plan does not misinterpret this as a form letter.
4. If you have questions, please contact 1.800.CARDIAC and ask for WATCHMAN Reimbursement.

[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 the WATCHMAN™ Left Atrial Appendage Closure (LAAC) Implant**

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 well as a description of the procedure.

***Background and Historical Treatment***

Atrial fibrillation (AF) is the most common cardiac arrhythmia, currently affecting more than 3 million Americans. In AF, the left atrium does not beat - instead it fibrillates meaning that it barely moves. Because of this, AF patients have a five-fold increased risk of stroke due to blood pooling in the left atrium and left atrial appendage (LAA). The pooled blood can form blood clots (i.e., thrombus formation), which can break off and go into the systemic circulation and lodge somewhere else in the body. Most commonly, these clots will lodge in the brain causing a stroke. Ninety-one percent of left atrial thrombi in non-valvular atrial fibrillation have been shown to be isolated to, or originate in, the LAA.[[1]](#footnote-1) The most common treatment for reducing the risk of these strokes from forming is using a medication called warfarin. Warfarin has been used for many years and works by interfering with the body’s clot forming mechanisms. Despite its proven efficacy, long-term warfarin therapy is not well-tolerated by some patients, has a very narrow therapeutic range, and carries a high risk for bleeding complications.

***The WATCHMAN™ Device***

The WATCHMAN™ Technology was developed with these patients specifically in mind (i.e., those that can tolerate warfarin but seek an alternative to long-term warfarin therapy) in providing risk reduction of stroke for those with non-valvular atrial fibrillation. The approved indication is as follows:

The WATCHMAN Device is indicated 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[[2]](#footnote-2) scores and are recommended for anticoagulation therapy;
* Are deemed by their physicians to be suitable for warfarin; and
* Have an appropriate rationale to seek a non-pharmacologic alternative to warfarin, taking into account the safety and effectiveness of the device compared to warfarin.

The WATCHMAN Left Atrial Appendage Device (WATCHMAN Device) is an implant that acts as a physical barrier, sealing the LAA to prevent thromboemboli from entering into the arterial circulation from the LAA, thereby reducing the risk of stroke and potentially eliminating the need for warfarin therapy in those patients with non-valvular AF who are eligible for warfarin.

Implant of the WATCHMAN Device may be done under local or general anesthesia in a cardiac catheterization laboratory. The WATCHMAN Device is implanted percutaneously via a transcatheter approach, using a standard transseptal technique.

***Clinical literature supporting evidence of WATCHMAN***

The WATCHMAN Device is one of the most studied devices to date with four complete clinical trials (PROTECT AF, CAP, PREVAIL AF, and CAP II) and over 2,400 patients implanted and over 6,000 patient years follow up. Results from the WATCHMAN clinical trial program have been published in acclaimed peer-reviewed journals with the most recent results from the PREVAIL AF trial and the PROTECT 4 year follow up.

The first study, a prospective, randomized study of the WATCHMAN LAAC technology (PROTECT AF) was published in the **Lancet** in August 2009.[[3]](#footnote-3) The efficacy results were very compelling in that 87% of the patients who received the device were successfully implanted and able to discontinue warfarin therapy at 45 days. Patients in the device group also had a 38% lower risk of all strokes, systemic embolism, and cardiovascular or unexplained death.

Results from a second study (CAP) were published in **Circulation** in January 2011.[[4]](#footnote-4) This continued access registry included a cohort of patients in the initial PROTECT AF study, and those from a non-randomized registry of patients undergoing a left atrial appendage closure implantation with the WATCHMAN Device. The study concluded that there was a significant decline in the rate of device and procedure-related complications between PROTECT AF and CAP.

The cadence and growing body of clinical evidence continues to support the medical value and safety of the WATCHMAN implant therapy. The PREVAIL study results were recently published (2014) in the **Journal of American College of Cardiology** support that WATCHMAN™ is successfully implanted by new operators and the results show low complication rates with both new and experienced operators compared to the early stages of the PROTECT AF trial.[[5]](#footnote-5) Lastly, the PROTECT AF four year data was published (2014) in the **Journal of American Medical Association** and showed a 29% reduction in primary efficacy events (all strokes, cardiovascular death, and systemic embolism) compared to warfarin therapy.[[6]](#footnote-6) In fact, it showed superiority to warfarin at 2,621 patient years or four years. The long term results of the PROTECT AF data present a compelling clinical benefit of the WATCHMAN Technology in being an alternative to warfarin for those patients that seek an alternative to long term oral anticoagulation in assessing the benefits vs. the risks.

Finally, the publication of the meta-analysis (2015) provides the randomized clinical trial and registry data supporting the totality of the evidence for the WATCHMAN therapy.[[7]](#footnote-7) Essentially, the totality of the clinical evidence reinforces the following conclusions:

1. Local therapy with WATCHMAN provides similar benefit to warfarin for the composite efficacy endpoint of stroke, systemic embolism or CV death
2. Compared with long-term warfarin, patients randomized to WATCHMAN have a significant improvement in survival, particularly freedom from CV death;
3. Although all-cause stroke rates are identical between groups, the pathophysiology of stroke was significantly different; more warfarin patients experiencing hemorrhagic strokes and more device patients experiencing ischemic strokes.
* Once accounting for the procedure-related events isolated to the early experience in PROTECT AF, there was not a statistical difference in the ischemic stroke rates seven days post procedure
1. By one year, approximately 95% of device patients discontinued warfarin;
2. Although all-cause bleeding was similar between groups, when peri-procedural bleeding was excluded, bleeding rates were significantly higher in patients treated with chronic warfarin;
3. Device performance was consistent over the entire data set – both randomized clinical trials and registries, the latter of which are likely to more closely resemble real world experience.

The WATCHMAN Device is FDA approved and it is the most studied LAAC device with the most patients and the only one with long-term clinical data.

***National Coverage Determination (NCD) establishes coverage for Percutaneous LAAC Therapy***

Effective on February 8, 2016, CMS has established positive coverage for percutaneous LAAC therapy (e.g., WATCHMAN) in its NCD when appropriate Medicare beneficiaries meet seven conditions for coverage. The NCD establishes uniform coverage and access to the WATCHMAN Device with specific patient criteria for LAAC eligibility that include the following:

* Patients must have a CHADS2 > 2 or CHA2DS2-VASc score > 3
* There must be documented evidence of a formal shared decision interaction between the patient and an independent, non-interventional physician utilizing an evidenced based tool for oral anticoagulants and AF management
* Must be suitable for warfarin but deemed unable to take long-term oral anticoagulation.

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&NcaName=Percutaneous+Left+Atrial+Appendage+(LAA)+Closure+Therapy&ExpandComments=n&DocID=281&DocType=nca&DocName=Percutaneous+Left+Atrial+Appendage+(LAA)+Closure+Therapy&bc=ACAAAAAAAgEAAA%3d%3d&).

Because your health plan either has no coverage criteria or non-covers percutaneous LAAC therapy, I am specifically requesting that you review the NCD criteria and apply it for reconsideration of my patient’s medical situation. My patient meets the eligibility criteria as follows: [***please complete as applicable]***

 [ ] CHADS2 score [ ]

 [ ] CHA2DS2- VASc score [ ]

 [ ] Eligible for short-term warfarin therapy but deemed unable to take long-term warfarin

[ ] Has a clinically meaningful reason for which the risk of long-term anticoagulation outweighs the benefit: ***[state reason(s) here]***

***Patient Medical necessity for WATCHMAN Implant therapy***

I have discussed the procedure with my patient, ***(name)*** , in assessing the benefits and risks of this therapyand my patient has made the decision to have the WATCHMAN Device implanted with hopes of eliminating his/her continued necessity for the long-term use of warfarin.

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

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]***

**[*Include the following if you determine to be applicable:]***

After receiving the WATCHMAN procedure, ***(patient name)*** will be able to discontinue the use of warfarin and eliminate the drug’s side effects and impact on ***(his/her)*** quality of life. In addition, as it has been proven in the published clinical research, the insertion of the WATCHMAN™ device may reduce the possible occurrence of stroke and systemic thromboembolism as it relates to thromboemboli originating in the left atrial appendage.

**[*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 and the WATCHMAN implant procedure has a similar risk profile. 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

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]***

1. Blackshear JL, Odell JA. Appendage obliteration to reduce stroke in cardiac surgical patients with atrial fibrillation. *Ann Thorac Surg*. 1996; 61:755-59. [↑](#footnote-ref-1)
2. January CT, Wann LS, Alpert JS, et. al., 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society, Circulation, 2014; 130: e199-e267. [↑](#footnote-ref-2)
3. Holmes D, Reddy V, Turi Z, et al. Percutaneous closure of the left atrial appendage versus warfarin therapy for prevention of stroke in patients with atrial fibrillation: A randomized non-inferiority trial. Lancet. 2009. 374: 534-42. [↑](#footnote-ref-3)
4. Reddy V, Holmes D, Doshi S, et al. Safety of percutaneous left atrial appendage closure: Results from the WATCHMAN left atrial appendage system for embolic protection in patients With AF (PROTECT AF) clinical trial and the Continued Access Registry. Circulation. Vol 123, 2011. [↑](#footnote-ref-4)
5. Holmes DR, Kar S, Price M, Whisenant B, Sievert H, Doshi S, Huber K, Reddy V. Prospective randomized evaluation of the Watchman left atrial appendage Device in patients with atrial fibrillation versus long-term warfarin therapy; the PREVAIL trial. Journal of the American College of Cardiology, Vol. 4, No. 1, 2014, 1-11. [↑](#footnote-ref-5)
6. Reddy VY, Sievert H, Halperin J, et al. Percutaneous Left Atrial Appendage Closure vs Warfarin for Atrial Fibrillation: A randomized clinical trial. JAMA. 2014;312(19): 1988-1998. [↑](#footnote-ref-6)
7. Holmes DR, Jr., Doshi SK, Kar S, et al. Left Atrial Appendage Closure as an Alternative to Warfarin for Stroke Prevention in Atrial Fibrillation: A Patient-Level Meta-Analysis. J Am Coll Cardiol. 2015;65(24):2614-2623. doi:10.1016/j.jacc.2015.04.025. [↑](#footnote-ref-7)