Clinical Policy Title: Watchman device

Clinical Policy Number: CCP.1356

Effective Date: March 1, 2018
Initial Review Date: January 11, 2018
Most Recent Review Date: February 5, 2019
Next Review Date: February 2020

Related policies:
None.

ABOUT THIS POLICY: AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas’ clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas’ clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas’ clinical policies are not guarantees of payment.

Coverage policy

AmeriHealth Caritas considers the use of left atrial appendage occlusion (e.g., Watchman device) for nonvalvular atrial fibrillation to be investigational, and therefore, not medically necessary.

Limitations:

N/A.

Alternative covered services:

Routine patient evaluation and management by a network health care provider.

Background
Atrial fibrillation due to valvular heart disease is an important cause of stroke and is conventionally treated with long-term oral anticoagulants that reduce the stroke risk but increase the risk of serious bleeding. Patients with nonvalvular atrial fibrillation have a more precarious situation, with a four- to five-fold increase in incidence of stroke and in the aggregate constitute 15 percent to 20 percent of strokes overall (Holmes, 2016).

As an alternative to oral anticoagulants for patients with nonvalvular atrial fibrillation, at least eight left atrial appendage occlusion devices have been developed in the past two decades. Among these are the Watchman device™ (Boston Scientific), Lariat suture delivery device™ (SentreHeart), Amplatzer Amulet™ (St. Jude Medical), Amplatzer Cardiac Plug™ (St. Jude Medical), and AtriClip™ (AtriCure).

The Watchman device is the only left atrial appendage occlusion device tested in randomized trials and approved by the U.S. Food and Drug Administration, on March 13, 2015 (Schellinger, 2018). In early 2016, Medicare began to cover the procedure under certain conditions (Centers for Medicare & Medicaid Services, 2016).

Multiple novel oral anticoagulants (e.g., apixaban, dabigatran, edoxaban, and rivaroxaban) and left atrial appendage closure devices have recently emerged as alternatives to vitamin K antagonists for stroke prophylaxis in nonvalvular atrial fibrillation. Moreover, site-specific therapy directed at left atrial appendage occlusion is technically possible, with one device for this indication already Food and Drug Administration-approved (the Watchman device). It is indicated in patients with nonvalvular atrial fibrillation, with acceptable anatomy, who are at increased risk for stroke and would be candidates for anticoagulation in whom there is concern about the risk-benefit ratio for chronic anticoagulation.

The Watchman device comes in five sizes: 21, 24, 27, 30, and 33 mm (Möbius-Winkler, 2012). A transesophageal electrocardiogram provides documentation of the absence of thrombi within the left atrial appendage and is helpful to determine the appropriate sized Watchman device to be implanted. A protocol for preimplantation assessment of the left atrial anatomy is attached in Appendix A.

Complications of device placement include embolization into the aorta or the left atrium. This can be successfully managed by percutaneous techniques in most cases, but device embolization into the left ventricle generally requires surgical retrieval, increasing overall procedure-related morbidity. In the eyes of many experts, the risk-benefit ratio of left atrial appendage closure versus systemic therapy (i.e., warfarin) for prevention of stroke, systemic embolism, and cardiovascular death in nonvalvular atrial fibrillation warrants cautious implementation in a select cohort of patients in whom anticoagulation for stroke prevention is contraindicated.

**Searches**

AmeriHealth Caritas searched PubMed and the databases of:
- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality.
We conducted searches on November 15, 2018. Search terms were: “left atrial appendage occlusion,” “nonvalvular atrial fibrillation,” and “Watchman.”

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.

- **Guidelines based on systematic reviews**.

- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

No device for left atrial appendage occlusion, including Watchman, is mentioned in guidelines for atrial fibrillation treatment (Brieger, 2018; European Society of Cardiology, 2016; January, 2014).

The first randomized controlled trial comparing the Watchman device with warfarin was called the PROTECT trial. Subjects included adults with nonvalvular atrial fibrillation with previous stroke or transient ischemic attack, congestive heart failure, diabetes, hypertension, or were 75 years or older. The trial included 463 patients assigned to percutaneous closure of the left atrial appendage (using the Watchman) and subsequent discontinuation of warfarin; and 244 to warfarin treatment for 45 days followed by clopidogrel and aspirin for six months. The primary efficacy event rate was lower (superior) among the Watchman group (3.0 versus 4.9 per 100 patient-years). The adverse event rate was higher (inferior) in the Watchman group (7.4 versus 4.4 per 100 patient-years) (Holmes, 2009).

The PROTECT trial findings were updated after an average follow up of 3.8 years, the rate of primary events, such as stroke, was significantly lower (superior) for the Watchman group (8.4 versus 13.9 percent, Risk Ratio = 0.60). The Watchman group had a significantly lower cardiovascular mortality rate (3.7 versus 9.0 percent, \( P = .005 \)) and all-cause mortality (12.3 versus 18.0 percent, \( P = .04 \)) (Reddy, 2014).

The PREVAIL study, which followed the PROTECT study, compared 269 patients of nonvalvular atrial fibrillation with a Watchman implant and discontinuation of warfarin compared with 138 patients with chronic warfarin therapy. After 18 months follow up, the total rate of stroke, systemic embolism, and cardiovascular/unexplained death were similar between the groups (.064 versus .063). The Watchman group was superior for rate of stroke or systemic embolism (.0200 versus .0253). Compared to the PROTECT study, lower rates were found for adverse events (4.2 versus 8.7 percent, \( P = .004 \)), pericardial
effusions requiring surgical repair (0.4 versus 1.6 percent, \(P = .027\)), and those requiring pericardiocentesis (1.5 versus 2.9 percent, \(P = .36\)) (Holmes, 2014).

In a follow-up study of the PREVAIL and PROTECT trials, each of the 1,114 patients in the Watchman or warfarin groups was followed for at least five years after the procedure. In PREVAIL, the risk of stroke, systematic embolism, or cardiovascular/unexplained death was not superior for Watchman. In the meta-analysis of both studies, risk was similar for both Watchman and warfarin for all adverse outcomes \((P = .27)\) and for stroke/systematic embolism \((P = .87)\). Rates were significantly lower for the Watchman patients for hemorrhagic stroke \((P = .0022)\), disabling/fatal stroke \((P = .03)\), cardiovascular/unexplained death \((P = .027)\), all-cause death \((P = .035)\), and post-procedure bleeding \((P = .0003)\) (Reddy, 2017). Results were similar to a study of PREVAIL and PROTECT, plus EWOLUTION and registry patients, with a median follow up of 2.69 years (Holmes, 2015).

A (non-randomized) continuous access protocol registry study of Watchman, included 542 PROTECT trial patients plus 460 new registry patients treated subsequent to the PROTECT patients. Newer patients had significantly lower rates for device-related safety events (3.7 versus 7.7 percent, \(P = .007\)); serious pericardial effusion (2.2 versus 5.0 percent, \(P = .019\)); and procedure-related stroke (0.0 versus 0.9 percent, \(P = .039\)). Significant disability or death rates were lower in the Watchman group (Reddy, 2011).

The EWOLUTION (non-randomized) study of Watchman performance included 1,021 patients at high risk of stroke. The Watchman device was successfully deployed in 98.5 percent of patients. The rate of serious adverse effects within one day of implant was 3.0 percent and the overall 30-day mortality rate was 0.7 percent. The rate of significant adverse effects within 30 days was significantly lower for subjects ineligible for oral anticoagulation therapy (6.5 versus 10.2 percent, \(P = .042\)) (Boersma, 2016).

An update of EWOLUTION reported a one-year mortality of 9.8 percent, which authors attributed to advanced age of subjects (mean 73.4 years) and presence of comorbidities (31.3 percent with a history of major bleeding and previous transient ischemic attack/ischemic stroke present in 30.5 percent). The ischemic stroke rate was 1.1 percent, 16 percent lower than similar patients; the major bleeding rate was 2.6 percent, about nine of 10 of which were not device- or procedure-related (Boersma, 2017).

A study of 1,005 EWOLUTION patients implanted with the Watchman device revealed 605 patients received dual antiplatelet therapy, which was discontinued within one year in 85 percent of patients. One year after implant, the ischemic stroke rate was 1.4 percent, below the expected of 7.5 percent; the major bleeding rate of 2.5 percent, below the expected 5.1 percent (Bergmann, 2018).

Large systematic reviews/meta-analyses (up to 246,005 patients) of left atrial appendage occlusion combine Watchman with other treatment modes. Watchman devices only include a small percentage of subjects from the PROTECT and PREVAIL clinical trials (n=732), limiting the importance of findings. A few specify results for Watchman versus warfarin, including:
• A meta-analysis of 14 studies (n=246,005) included 732 Watchman patients. Superior results in preventing hemorrhagic stroke versus warfarin was observed for Watchman (Odds Ratio = 0.21). Comparisons between new oral anti-coagulants and Watchman showed no significant differences in outcomes, but with Watchman did identify a trend toward higher rates of ischemic stroke (2.60) and lower rates of hemorrhagic stroke (0.44) (Koifman, 2016).

• A meta-analysis of six studies (n=59,627) included mostly apixaban, dabigatran, edoxaban, and rivaroxaban versus vitamin K antagonists. The WATCHMAN left atrial appendage closure device ranked last in safety and efficacy compared to the four treatments listed (Bajaj, 2016).

• A meta-analysis of 16 studies (n=1,759) found left atrial appendage occlusion devices, including Watchman, reduced stroke risk compared to no therapy or aspirin therapy (Relative Risk 0.34) and compared to warfarin therapy (0.65). No differences were found in efficacy and safety for Watchman and other devices (Bode, 2015).

• A systematic review/meta-analysis of seven studies (n=73,978) compared novel oral anticoagulants, Watchman and warfarin. No difference was observed between Watchman and warfarin for systemic embolism, all-cause mortality, and safety outcomes, and Watchman had more complication (P = .012). Authors concluded that Watchman should be used carefully given existing safety concerns (Briceno, 2015).

• Similarly, no difference in outcomes of Watchman and oral anticoagulants was observed in a systematic review of 20 trials (Noelck, 2016).

• A meta-analysis of 21 randomized trials (n=96,017) found that in comparison to placebo/control, reduction in risk of stroke/systemic embolism for Watchman (Odds Ratio 0.36) was more effective than aspirin (0.75), vitamin K antagonists (0.38), and edoxaban (0.38), but less effective as apixaban (0.31, dabigatran (0.29), and rivaroxaban (0.27). The Watchman reduction in risk of all-cause mortality (0.47), exceeded that of aspirin (0.82), vitamin K antagonists (0.69), apixaban (0.62), dabigatran (0.62), edoxaban (0.62), and rivaroxaban (0.58) (Tereshchenko, 2016).

A review of quality of life for patients in the PREVAIL/PROTECT trials assessed quality of life changes. Total physical score was better for Watchman patients (improved in 34.9 percent, unchanged in 29.9 percent) compared to the warfarin group (24.7 percent and 31.7 percent), P = .01. Mental health improvement was greater for the Watchman group (33.0 versus 22.6 percent, P = .06) (Alli, 2013).

Policy updates:

A total of three guidelines/other and 11 peer-reviewed references were added to, and one guideline/other and four peer-reviewed references removed from this policy in November 2018.

The policy number was changed from CP#04.03.09 to CCP.1356 in November, 2018.

References

Professional society guidelines/other:


**Peer-reviewed references:**


**Centers for Medicare and Medicaid Systems National Coverage Determinations:**

20.34 National Coverage Determination for Percutaneous Left Atrial Appendage Occlusion.

**Local Coverage Determinations:**

No Local Coverage Determinations identified as of the writing of this policy.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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<th>Description</th>
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<td>93318</td>
<td>Echocardiography, transesophageal (TEE) for monitoring purposes, including probe placement, real time 2-hyphen-dimensional image acquisition and interpretation leading to ongoing (continuous) assessment of (dynamically changing) cardiac pumping function and to therapeutic measures on an immediate time basis</td>
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<table>
<thead>
<tr>
<th>ICD-10 Code</th>
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<tr>
<td>I63.30 - I63.9</td>
<td>Cerebral infarction [stroke]</td>
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<tr>
<td>I66.01 - I66.9</td>
<td>Occlusion and stenosis of cerebral arteries, not resulting in cerebral infarction [stroke]</td>
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### Appendix A

Protocol for implantation of the Watchman device (Möbius-Winkler, 2012)

The WATCHMAN device frame is constructed of nitinol (a nickel/titanium alloy) and is composed of 10 fixation anchors around the device perimeter that are designed to secure the device in the left atrial appendage.

A fabric cap, constructed out of fabric polyethyl terephthalate serves as a 160-micron filter and prevents harmful emboli from exiting during the healing process.

1. The device comes in five different sizes: 21, 24, 27, 30, 33 mm, and the contoured shape of the device accommodates most left atrial anatomy.

2. The WATCHMAN Trans-septal Access System is available in double or single curve styles (14 French [F] Outer Diameter 4.7 mm, 12F Inner Diameter with a 75 cm working length.

3. The device is preloaded (constrained) within the 12F delivery catheter. Note: The WATCHMAN delivery system is compatible with all 5 device sizes (12F outer diameter).

Procedure:

Transesophageal echocardiogram-based determination of WATCHMAN device size

1. Prior to starting the procedure, a transesophageal echocardiogram is performed to document the absence of thrombi within the left atrial appendage and to determine the appropriate sized WATCHMAN device to be implanted. The recommended international normalized ratio should be $\geq 1.5$ to perform the implantation procedure.

2. With the patient under conscious sedation (e.g. midazolam 2 mg – 5 mg), pass the ultrasound probe into the esophagus.

3. Confirm the absence of left atrial/ left atrial appendage thrombus.
4. Assess the following left atrial appendage features: ostium size and shape, number of lobes, location, working length in the left atrial appendage, and pectinate features. The maximum left atrial appendage ostium size should be >17mm or <31mm to accommodate available WATCHMAN device sizes.

5. To do this, measure the left atrial appendage ostium in at least four transesophageal echocardiogram views. First measure the ostium at 0 degrees from the left coronary artery to a point 2 cm from tip of the left upper pulmonary vein limbus. Then measure it at 45, 90, and 135 degrees from the top of the mitral valve annulus to a point 2 cm from tip of the left upper pulmonary vein limbus.

6. Measure the approximate left atrial appendage usable length from the ostium line to the apex of the left atrial appendage. The available/useable left atrial appendage length should be equal to or greater than the largest distance measured.

7. To aid in planning the approach, categorize the left atrial appendage type: most can be categorized as "WindSock type," "ChickenWing type," or "Broccoli type." With the left atrial appendage form categorized, the difficulty of the implantation procedure can be estimated.

8. The WindSock type left atrial appendage is an anatomy in which one dominant lobe of sufficient length is the primary structure. The implantation procedure in most of these cases is relatively easy to perform.

9. The ChickenWing type left atrial appendage is an anatomy whose main feature is a sharp bend in the dominant lobe of the left atrial appendage anatomy at some distance from the perceived left atrial appendage ostium.

10. If the proximal part longer than the widest diameter the implant procedure is straightforward. However, if the proximal part is shorter than the maximum width of the left atrial appendage orifice, the procedure may be complicated.

11. The Broccoli type left atrial appendage is an anatomy whose main feature is a left atrial appendage that has limited overall length with more complex internal characteristics. When this anatomy is present, the device is often difficult to implant since there are several lobes to cover and the length of the left atrial appendage is limited.