Medical Necessity Guidelines: Percutaneous Left Atrial Appendage Closure to Reduce Stroke Risk in Patients with Atrial Fibrillation (Watchman™ Device)

Effective: November 18, 2020

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	**Yes ☐ No ☒**

Applies to:

COMMERCIAL Products

☒Tufts Health Plan Commercial products; Fax: 617.972.9409

☒Tufts Health Freedom Plan products; Fax: 617.972.9409

- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

TUFTS HEALTH PUBLIC PLANS Products

☒Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax:888.415.9055

☒Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax: 888.415.9055

☒Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax: 857.304.6404

☒Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax: 857.304.6304

*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

SENIOR Products

- Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product) – Refer to the Tufts Health Plan SCO Prior Authorization List
- Tufts Medicare Preferred HMO, (a Medicare Advantage product) – Refer to the Tufts Medicare Preferred HMO Prior Authorization and Inpatient Notification List

OVERVIEW

Atrial fibrillation (AF) is a rapid, irregularly irregular atrial cardiac rhythm brought on when the two upper chambers (atria) of the heart no longer contract together in a coordinated manner. AF is one of the most common arrhythmias, affecting about 2.3 million adults in the US. Prevalence increases with age; almost 10% of people over the age of 80 are affected. AF tends to occur in patients with a heart disorder. Atrial thrombi often form in patients with AF due to the slowing of blood flow that results when the atria no longer contract normally, causing a significant risk of embolic stroke.

The WATCHMAN LAA closure technology consists of a delivery catheter and a device that is permanently implanted in the left atrial appendage (LAA) of the heart. The device, often referred to as the WATCHMAN, prevents LAA blood clots from entering the bloodstream and potentially causing a stroke. It is used in patients who have atrial fibrillation not related to heart valve disease.

CLINICAL COVERAGE CRITERIA

Tufts Health Plan may cover percutaneous left atrial appendage (LAA) closure using the Watchman device when medically necessary to reduce the risk of thromboembolism from the LAA in patients with nonvalvular atrial fibrillation who:

- Are at increased risk for stroke and systemic embolism;
- 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.

LIMITATIONS

Percutaneous left atrial appendage closure using any device other than the WATCHMAN device is considered investigational and, therefore, not covered (including but not limited to Amplatzer Cardiac Plug (ACP), Amplatzer Amulet, and Lariat suture delivery device). Please also refer to the Medical Necessity Guideline: Noncovered Investigational Services.

CODES

Table 1: CPT Codes

CPT Code	Description
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

ICD-10 diagnosis codes associated with the above procedure code(s) include:

Table 2: ICD-10 Codes

ICD-10 Code	Description
I48.0	Paroxysmal atrial fibrillation
I48.11	Longstanding persistent atrial fibrillation
I48.19	Other persistent atrial fibrillation
I48.20	Chronic atrial fibrillation, unspecified
I48.21	Permanent atrial fibrillation

REFERENCES

1. Merck & Co. Inc. Merck Manual Professional Version. Atrial Fibrillation. Available at merckmanuals.com/professional. Accessed March 11, 2016.
2. Hayes, Winifred S. Directory Report. Percutaneous Left Atrial Appendage Closure to Reduce Stroke Risk in Patients with Atrial Fibrillation. July 2, 2015. Available at hayesinc.com. Accessed March 7, 2016.
3. United States Food and Drug Administration. Report: WATCHMAN LAA Closure Technology-P130013. Medical Devices, Recently-Approved Devices. Available at fda.gov. Accessed March 11, 2016.

APPROVAL HISTORY

April 13, 2016: Reviewed by the Integrated Medical Policy Advisory Committee (IMPAC), for effective date of October 1, 2016.

Subsequent endorsement date(s) and changes made:

- December 14, 2016: Reviewed by IMPAC, renewed without changes
- December 31, 2016: Coding updated. Per AMA CPT®, effective December 31, 2016 the following code(s) deleted: 0281T; and effective January 1, 2017 the following code(s) added: 33340.
- April 2017: Added RITogether Plan product to template. For MNGs applicable to RITogether, effective date is August 1, 2017
- December 13, 2017: Reviewed by IMPAC, renewed without changes.
- June 13, 2018: Reviewed by IMPAC, update to limitations section.
- October, 2018: Template and disclaimer updated
- November 14, 2018: Reviewed by IMPAC, renewed without changes
- November 20, 2019: Reviewed by IMPAC, renewed without changes
- September 10, 2020: ICD-10 coding update
- November 18, 2020: Reviewed by IMPAC, renewed without changes
- December 8, 2020: Fax number for Unify updated

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Medical Necessity Guidelines are developed to determine coverage for benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government

agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.