Transcatheter Closure of Septal Defect

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Policy

The Medical Management Department reviews referral requests for authorization of transcatheter closure of Atrial Septal Defect (ASD), Patent Foramen Ovale (PFO), and Ventricular Septal Defect (VSD).

This Medical Policy does not constitute medical advice. When deciding coverage, the enrollee's specific plan document must be referenced. The terms of an enrollee's plan document (Certificate of Coverage (COC) or Summary Plan Description (SPD)) may differ from this Medical Policy. In the event of a conflict, the enrollee's specific benefit plan document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements, and the plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. Quartz reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

Procedure

I. Transcatheter Closure of Atrial Septal Defect (ASD)

A. Documentation Required

1. In order to facilitate the authorization process for a secundum Atrial Septal Defect (ASD), the referral requests must include the following:
    a. Physician detailed physical exam and medical history detailing the atrial septal defect that requires closure; for **ONE** of the following indications:
        i. For patients who have echocardiographic evidence of ostium secundum ASD; **OR**
        ii. For patients who have undergone a fenestrated Fontan procedure and who now require closure of the fenestration.

B. Medical Necessity Criteria

1. Transcatheter closure of an atrial septal defect using an FDA approved device is considered medically necessary for **EITHER** of the following indications for pediatric or adult patients:
    a. For the occlusion of an Atrial Septal Defect in secundum position with documented net left to right shunt (Qp:Qs is 1.5:1 or greater); **OR**
    b. For the closure of the fenestration following a fenestrated Fontan procedure.

II. Transcatheter Closure of Patent Foramen Ovale (PFO)

A. Documentation Required

1. In order to facilitate the authorization process for percutaneous transcatheter closure of a PFO, the referral request must include **ALL** of the following:
    a. Cardiac imaging confirming the presence of a PFO with a right-to-left interatrial shunt detected by bubble study;
    b. Cerebral imaging that identifies a stroke with likelihood that it was embolic in nature;

c. Documentation from both a neurologist and cardiologist that agree that PFO closure is reasonable to prevent a recurrent stroke event;
d. A calculated RoPE score;
e. Results of at least a 14-day cardiac event monitoring documenting the absence of atrial fibrillation or atrial flutter;
f. Documentation of other tests performed to exclude other causes of ischemic stroke.

B. Medical Necessity Criteria

1. Percutaneous transcatheter closure of a PFO using an FDA approved device is considered medically necessary when **BOTH** of the following are met:
   a. Patients 18 to 60 years of age who have had a documented cryptogenic stoke due to a presumed paradoxical embolism, as determined by a neurologist and cardiologist; **AND**
   b. Known causes of ischemic stroke have been excluded.

III. Transcatheter Closure of Ventricular Septal Defect (VSD)

A. Documentation Required

1. In order to facilitate the authorization process for percutaneous transcatheter closure of a VSD, the referral request must include **BOTH** of the following:
   a. Cardiac imaging confirming the presence of a VSD;
   b. Cardiac testing results with hemodynamics.
   c. Explanation for why the patient transcatheter approach is suitable for this and/or why the patient is not a surgical candidate and procedure should be done via the transcatheter approach.
   d. Patient evaluated by a Cardiologist and a Cardiothoracic Surgeon who both agree that the transcatheter approach is the best approach.

B. Medical Necessity Criteria

1. Percutaneous transcatheter closure of a VSD using an FDA approved device is considered medically necessary in children or adults with **ALL** the following:
   a. The VSD has a net left to right shunt (Qp:Qs > 1.5:1), **AND**
   b. The VSD is hemodynamically significant, i.e., patient is symptomatic or having signs of left ventricular volume overload.

IV. Indications Considered Experimental, Investigational or not Medically Necessary: (*Not all-inclusive*)

1. Transcatheter closure of ostium primum or sinus venosus atrial septal defects (ASDs) is considered experimental, investigational, or unproven.
2. Preventricular (transmyocardial) closure of ventricular septal defects (VSDs) is considered investigational, experimental or unproven for all other indications.
3. Transcatheter closure of an ASD while the patient has active endocarditis or a systemic infection.
4. Transcatheter closure of a secundum ASD or VSD with net right-to-left shunt or Eisenmenger's syndrome.
5. Transcatheter closure of PFO in patient with documented atrial fibrillation or atrial flutter.
6. Transcatheter closure of PFO for treatment of transient ischemic attacks, migraine prophylaxis or any other indications not noted in approval criteria above because its effectiveness for these indications has not been established.
7. Transcatheter closure of PFO in patient who is on lifelong/chronic anticoagulation for another indication, e.g., recurrent deep venous thrombosis.

CPT/HCPCS CODES:

C1817	Septal defect implant system, intracardiac
93580	Percutaneous transcatheter closure of congenital interatrial communication (i.e., Fontan fenestration, atrial septal defect) with implant

REFERENCES:

Hayes, Inc. Medical Technology Directory. Transcatheter closure of patent foramen ovale for prevention for recurrent cryptogenic stroke. Publication date May 31, 2018. Accessed June 12, 2019.

January CT, Wann S, Alpert JS, et al. 2014 AHA/ACC/HRS practice guideline. 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.

Mas JL, Derumeaux G,m Guillon B, et al. Patent foramen ovale closure or anticoagulation v antiplatelets after stroke. N Engl J Med. 2017;377(11):1011-1021.

Masoudi FA, Caukins H, Kavinsky CJ, et al. 2015 ACC/HRS/SCAI left atrial appendage occlusion device societal overview. A professional societal overview from the American College of Cardiology, Heart Rhythm Society, and Society for Cardiovascular Angiography and Interventions. J Am Coll Cardiol. 2015;66:1497-1513.

Saver JL, Carroll JD, Thaler DE, et al. Long-term outcomes of patent foramen ovale closure or medical therapy after stroke. N Engl J Med. 2017;377(11):1022-1032.

Sondergaard L, Kasner SE, Rhodes JF, et al. Patent foramen ovale closure or antiplatelet therapy for cryptogenic stroke. N Engl J Med. 2017;377(11):1033-1042.

Stout KK, Daniels CJ, Aboulhosn JA, et al. 2018 AHA/ACC Guideline for the Management of Adults with Congenital Heart Disease: Executive Summary: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol. 2019;139:e637-e697.

U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH). Summary of Safety and Effectiveness: Amplatzer® PFO Occlusion System. Humanitarian Device Exemption No. H000007. Rockville, MD: April 5, 2002. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals/ucm161827.htm.

U.S. Food and Drug Administration (FDA). Center for Devices and Radiological Health (CDRH); GORE HELEX Septal Occluder. Premarket approval. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf5/p050006b.pdf.