



Transcatheter Closure of Septal Defect

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Policy

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;
 - 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 for patients aged 18 – 65 years old when **ALL** of the following are met:
 - a. Documented cryptogenic stroke due to a presumed paradoxical embolism, as determined by a neurologist and cardiologist, **AND**
 - b. Known causes of ischemic stroke have been excluded; **AND**
 - c. There is agreement by both a cardiologist and a neurologist that PFO closure is medically necessary to prevent recurrent stroke, **AND**
 - d. Patients 61-65 years of age must meet **ONE** of the following:
 - i. Acute venous thromboembolism, e.g., documented deep venous thrombus, pulmonary embolism or other acute venous thrombosis, concurrent with the stroke and deemed as the most likely source of the paradoxical embolism, **OR**
 - ii. Absence of traditional vascular risk factors such as hypertension, diabetes, hyperlipidemia and smoking.

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 ($Q_p:Q_s > 1.5:1$), **AND**
 - b. The VSD is hemodynamically significant, i.e., patient is symptomatic or having signs of left ventricular volume overload.

IV. Indications Considered Experimental and Investigational: (Not an all inclusive list)

1. Transcatheter closure of ostium primum or sinus venosus atrial septal defects (ASDs).
2. Preventricular (transmyocardial) closure of ventricular septal defects (VSDs).
3. Transcatheter closure of a secundum ASD or VSD with net right-to-left shunt or Eisenmenger's syndrome.
4. Transcatheter closure of PFO in patient with documented atrial fibrillation or atrial flutter.

5. Transcatheter closure of PFO for treatment of migraine prophylaxis or any other indications not noted in approval criteria above because its effectiveness for these indications has not been established.

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

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