Clinical Policy Title: Transcatheter closure of septal defects

Clinical Policy Number: 04.03.10

Effective Date: April 1, 2018
Initial Review Date: February 6, 2018
Most Recent Review Date: March 6, 2018
Next Review Date: March 2019

Related policies:

CP# 04.03.09 Watchman device

ABOUT THIS POLICY: Select Health of South Carolina has developed clinical policies to assist with making coverage determinations. Select Health of South Carolina’s 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 Select Health of South Carolina 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. Select Health of South Carolina’s 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. Select Health of South Carolina’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Select Health of South Carolina will update its clinical policies as necessary. Select Health of South Carolina’s clinical policies are not guarantees of payment.

Coverage policy

Select Health of South Carolina considers the use of transcatheter closure of septal defects for acquired or congenital heart disease to be clinically proven and, therefore, medically necessary when the following criteria are met:

- Transcatheter closure device is Food and Drug Administration (FDA) approved

AND

- The device is implanted in a manner consistent with the manufacturers’ package insert directions (e.g., appropriate size of the device)

AND

- Indications for occlusion of atrial septal defect (ASD) are present (Law 2009), or
- Indications for occlusion of secundum atrial defects are present (Villablanca 2017, Atashband 2015), or
- Indications for occlusion of ventricular septal defect (VSD) are present (Yang 2014), or
- Indications for occlusion of perimembranous VSD are present (Santhanam 2017), or
- Indications for occlusion of postinfarction VSD are present (Zhang 2017), or
• Indications for occlusion of patent ductus arteriosus are present (Jin 2015)

Limitations:

Select Health of South Carolina considers the use of transcatheter closure of septal defects for migraine prophylaxis, secondary prevention of stroke, transient ischemic attacks, or paradoxical emboli to be investigational and, therefore, not medically necessary (Li 2015, Riaz 2013, Rengifo-Moreno 2013).

Alternative covered services:

• Routine patient evaluation and management by a network healthcare provider

Background

The most common congenital intracardiac defect in children is atrial septal defect (ASD), inclusive of patent foramen ovale (PFO) and secundum atrial defects. If untreated, any of these defects may lead to right ventricular failure, atrial arrhythmias, and pulmonary hypertension.

Since the initial description of an atrial septal defect closure device in the mid-1970s by King and Mills, transcatheter closure of ASD and PFO using various devices has become an established practice in many centers. Excellent occlusion rates with low complication rates have also been achieved in patent ductus arteriosus.

Secundum atrial septal defects are readily treated by surgical closure or transcatheter device closure. Due to a scarcity of data directly comparing these approaches, it remains unclear which is superior.

Advances in interventional techniques now allow for transcatheter treatment of some ventricular septal defects (VSDs), although concerns remain about adverse events; particularly heart block in perimembranous VSDs.

Postinfarction VSD is a rare but fatal complication after myocardial infarction. Surgery for postinfarction VSD is considered the gold standard. However, it is associated with high morbidity and mortality, patient discomfort, need of cardiopulmonary bypass, sternotomy, and skin scarring. As a consequence, less invasive interventional techniques have been developed for postinfarction VSD closure.

Searches

Select Health of South Carolina searched PubMed and the databases of:

• UK National Health Services Centre for Reviews and Dissemination.
• Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on January 2, 2018. Search terms were: "transcatheter closure," "septal defect," and "percutaneous cardiology."

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**

A systematic review (Yang 2014) assessed clinical outcomes from transcatheter closure in 4406 patients with VSD (perimembranous = 3,758, muscular = 419, intracristal = 47, doubly committed subarterial = 36, multiple = 16, postsurgical = 123, unclassified = 7). The age of patients ranged from 3 days to 84 years. The pooled estimate of successful device implantation was 96.6 percent (95% CI: 95.7-97.5). The most common complication is residual shunt (pooled estimated 25.5 percent; 95% CI: 18.9-32.1). Others included valvular defects (pooled estimate 4.9 percent; 95% CI: 3.4-6.4) and arrhythmias (pooled estimate 10.6 percent; 95% CI: 8.4-12.7). The authors concluded that transcatheter device closure of VSD is safe and yields good results; however, they identified the limitations of this study in analyzing different devices individually and segregating the different VSD types.

A clinical trial (Law 2009) examined transcatheter closure of ASD in patients age ≥2 years, isolated secundum ASD, evidence of right ventricular volume overload, and maximum stretched diameter <22 mm. Clinical success in the trial was defined as complete closure or residual leak ≤2 mm, absence of a severe complication and no need for an additional device or surgery to treat the ASD. Twenty seven patients were prospectively enrolled in the study period with a procedural success in 23 (85 percent). There were two severe complications, both 40 mm device emboliations that underwent semiurgent surgical intervention for device removal and ASD closure (40 mm device subsequently withdrawn from trial). Device placement was unsuccessful in two patients due to malposition related to an insufficient retro-aortic rim, with elective surgical closure. Unsuccessful procedural outcomes were statistically associated with deficient rims (P < 0.01). Of the 23 long term follow-up device patients, 23 (100 percent) achieved clinical success: 22 (96 percent) had complete closure at one year and latest echocardiographic follow-up and one case had a small <2 mm residual defect that has persisted. Fractures occurred in eight (35 percent) of devices and were more common in the larger devices (P < 0.05).
A systematic review and meta-analysis (Rengifo-Moreno 2013) evaluated transcatheter closure of PFO compared to medical therapy (n=2,303) in patients who suffered cryptogenic stroke. Patients were randomized to PFO closure (n=1150) and 1,153 patients randomized to medical therapy. Intention-to-treat analyses showed a statistically significant risk reduction in stroke and/or transient ischemic attack in the PFO closure group when compared to medical treatment, pooled HR = 0.59, 95%CI (0.36-0.97), P = 0.04. The combined outcome of death, and vascular events, showed a borderline statistically significant benefit for PFO closure when compared to medical treatment, pooled HR = 0.67, 95%CI (0.44-1.00), P = 0.05 Subjects with a substantial PFO shunt seem to benefit the most with closure, pooled HR = 0.35, 95%CI (0.12-1.03), P = 0.06, however, it did not reach statistical significance.

A systematic review and meta-analysis (Santhanam 2017) sought to determine if transcatheter device closure of perimembranous VSDs (n=6762) is a safe and effective procedure for closure of perimembranous VSDs through end-February 2017. The mean age of patients ranged from 1.6 to 37.4 years. The pooled estimate of successful device implantation was 97.8 percent (95% CI: 96.8 to 98.6). The most common complication is residual shunt (15.9 percent; 95% CI: 10.9 to 21.5). Other complications include arrhythmias (10.3 percent; 95% CI: 8.3 to 12.4) and valvular defects (4.1 percent; 95% CI: 2.4 to 6.1). The pooled estimate of complete atrioventricular block was 1.1 percent (95% CI: 0.5 to 1.9). The authors concluded that device closure of perimembranous VSDs is a safe and effective procedure but advised that prospective studies are needed to evaluate efficacy of percutaneous ASD closure in adults with large defects, higher shunt ratios, and severe pulmonary hypertension.

A retrospective clinical study (Zhang 2017) evaluated the safety and efficacy of percutaneous interventional closure of postinfarction ventricular septal defects in 12 patients who underwent occlusion rather than surgery. The mean defect size was 14.20 ± 4.89 mm. Those who survived had higher systolic blood pressure, diastolic blood pressure, and left ventricular ejection fraction upon admission, as well as lower pulmonary/systemic flow ratio and shorter time from acute myocardial infarction to procedure. The incidence of cardiac shock and heart failure was lower in the survival group than in the death group, and these factors correlated with in-hospital and 30-day mortality. The authors concluded that percutaneous closure of postinfarction VSD is an effective technique, which can be performed with a high procedural success rate.

A systematic review and meta-analysis (Villablanca 2017) assessed treatment options for the closure of secundum atrial septal defects (n=14,559 patients). Transcatheter closure was superior to surgical closure with regard to all-cause mortality (RR, 0.66; 95% CI 0.64-0.99), total complications (RR, 0.48; 95% CI 0.35-0.65), major complications (RR, 0.57; 95% CI 0.40-0.81), minor complications (RR, 0.35; 95% CI 0.23-0.53), and length of stay (DM, -2.92; 95% CI -3.25 to (-2.58)). Residual shunts were more common with transcatheter closure (RR, 3.35; 95% CI 1.72-6.51). No difference was observed regarding the need of reintervention (RR, 1.45; 95% CI 0.60-3.51). Meta-regression analysis showed that older age increases the risk of death and complications in patients undergoing transcatheter closure.

A retrospective study (n= 1526; 537 boys, 989 girls) examined transcatheter occlusion of patent ductus arteriosus, including gender, age, weight, size and morphology of the defect, and devices used in
transcatheter occlusion, outcomes, and postoperative complications (Jin 2015). Median age and median weight were 4.0 years (range: 0.3-52.0 years old) and 15.3 kg (range: 4.5-91.0 kg), respectively. Mean ductal diameter, aortic ductal diameter, ductal length, and pulmonary artery pressure were 3.50 ± 2.15 mm, 10.08 ± 2.46 mm, 7.49 ± 3.02 mm, and 30.21 ± 17.28 mmHg, respectively. In summary, 1497 patients underwent transcatheter closure, among which 1492 were successful. Devices used were Amplatzer duct occluder I (n=1280, 85.8 percent), Cook detachable coils (n=116, 7.8 percent), Amplatzer duct occluder II (n=68, 4.6 percent), muscular VSD occluder (n=12, 0.8 percent), and Amplatzer vascular plug (n=16, 1.0 percent).

A randomized clinical trial (n=2303) evaluated medical therapy (antithrombotic treatment with antiplatelet agents or anticoagulants) versus transcatheter device closure for secondary stroke prevention (Li 2015). Intention-to-treat analyses did not show a statistically significant risk reduction in the composite endpoint of recurrent stroke or transient ischemic attack in the transcatheter closure group when compared with medical therapy (RR 0.73, 95% CI 0.45 to 1.17). A time-to-event analysis combining the results of two RCTs also failed to show a significant risk reduction with transcatheter device closure (HR 0.69, 95% CI 0.43 to 1.13). When assessing stroke prevention alone, transcatheter device closure still did not show a statistically significant benefit (RR 0.61, 95% CI 0.29 to 1.27) (HR 0.55, 95% CI 0.26 to 1.18). Safety analysis found that the overall risks for all-cause mortality and adverse events were similar in both the transcatheter device closure and medical therapy groups; however, transcatheter device closure increased the risk of new-onset atrial fibrillation (RR 3.50, 95% CI 1.47 to 8.35) and may be associated with the type of device used.

Atashband (2015) monitored adult patients (n=1958 patients) after percutaneous closure of isolated secundum atrial septal defects. Mean follow-up was 12.6 ± 4.9 months with a closure rate of 96.9 percent ± 1.4. Echocardiographic parameters of improvement included decrease in right ventricular volume from 157.2 to 100.2 mL (p = 0.02), right ventricular end-diastolic dimensions from 40.8 to 32.4 mm (p< 0.0001) and pulmonary artery systolic pressures from 42.2±2.2 to 34.4±2.4 (p < 0.0001). At the end of follow-up complications included one percent mortality rate, 0.8 percent device embolization, 5.8 percent new onset arrhythmias and 1.2 percent need for surgical closure.

A systematic review and meta-analysis (Riaz 2013) evaluated the safety and efficacy of transcatheter device closure (n = 1150) versus standard medical therapy in patients (n = 1153) with PFO and cryptogenic stroke. The primary outcome was a composite end-point of death, stroke and transient ischemic attack. Mean follow-up was 2.5 years. Transcatheter closure was not superior to medical therapy in the secondary prevention of stroke or transient ischemic attack in intention-to-treat analysis (HR: 0.66, 95% CI: 0.43 to 1.01; p = 0.056). However, the results were statistically significant using per-protocol analysis (HR: 0.64, 95% CI: 0.41 to 0.98; p = 0.043). Males had significant benefit with device closure (HR: 0.48, 95% CI: 0.24 to 0.96; p = 0.038).

Summary of clinical evidence:
<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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</thead>
<tbody>
<tr>
<td><strong>Villablanca (2017)</strong></td>
<td><strong>Key points:</strong></td>
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</table>
| Treatment options for the closure of secundum atrial septal defects: A systematic review and meta-analysis. | - Systematic review and meta-analysis assessed treatment options for the closure of secundum atrial septal defects (n=14,559 patients).  
- Transcatheter closure was superior to surgical closure with regard to all-cause mortality (RR, 0.66; 95% CI 0.64-0.99), total complications (RR, 0.48; 95% CI 0.35-0.65), major complications (RR, 0.57; 95% CI 0.40-0.81), minor complications (RR, 0.35; 95% CI 0.23-0.53), and length of stay (DM, -2.92; 95% CI -3.25 to (-2.58)).  
- Residual shunts were more common with transcatheter closure (RR, 3.35; 95% CI 1.72-6.51).  
- No difference was observed regarding the need of reintervention (RR, 1.45; 95% CI 0.60-3.51).  
- Meta-regression analysis showed that older age increases the risk of death and complications in patients undergoing transcatheter closure. |
| **Santhanam (2017)**     | **Key points:**                   |
| A meta-analysis of transcatheter device closure of perimembranous ventricular septal defect. | - Meta-analysis sought to determine if transcatheter device closure of perimembranous VSDs (n=6762) is a safe and effective procedure.  
- The mean age of patients ranged from 1.6 to 37.4 years.  
- The pooled estimate of successful device implantation was 97.8 percent (95% CI: 96.8 to 98.6).  
- The most common complication was residual shunt (15.9 percent; 95% CI: 10.9 to 21.5).  
- Other complications include arrhythmias (10.3 percent; 95% CI: 8.3 to 12.4) and valvular defects (4.1 percent; 95% CI: 2.4 to 6.1).  
- The pooled estimate of complete atrioventricular block was 1.1 percent (95% CI: 0.5 to 1.9).  
- Prospective studies are needed to evaluate efficacy of percutaneous ASD closure in adults with large defects, higher shunt ratios, and severe pulmonary hypertension. |
| **Zhang (2017)**         | **Key points:**                   |
| In-Hospital Outcomes and Long-Term Follow-Up after Percutaneous Transcatheter Closure of Postinfarction Ventricular Septal Defects. | - Retrospective study evaluated the safety and efficacy of percutaneous interventional closure of postinfarction ventricular septal defects in 12 patients who underwent occlusion rather than surgery.  
- The mean defect size was 14.20 ± 4.89 mm.  
- Those who survived had higher systolic blood pressure, diastolic blood pressure, and left ventricular ejection fraction upon admission, as well as lower pulmonary/systemic flow ratio and shorter time from acute myocardial infarction to procedure.  
- The incidence of cardiac shock and heart failure was lower in the survival group than in the death group, and these factors correlated with in-hospital and 30-day mortality.  
- The authors concluded that percutaneous closure of postinfarction VSD is an effective technique, which can be performed with a high procedural success rate. |
<p>| <strong>Atashband (2015)</strong>     | <strong>Key points:</strong>                   |
| First Comprehensive Analysis of Outcomes in | - First comprehensive analysis of adult patients (n=1958 patients) after percutaneous closure of isolated secundum atrial septal defects. |</p>
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| Adult Patients after Percutaneous Closure of Isolated Secundum Atrial Septal Defects. |  - Mean follow-up was 12.6 ± 4.9 months with a closure rate of 96.9 percent ± 1.4.  
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  - At the end of follow-up complications included one percent mortality rate, 0.8 percent device embolization, 5.8 percent new onset arrhythmias and 1.2 percent need for surgical closure. |
| Li (2015) | **Key points:**  
  - Randomized clinical trial (n=2303) evaluated medical therapy (antithrombotic treatment with antiplatelet agents or anticoagulants) versus transcatheter device closure for secondary stroke prevention.  
  - Intention-to-treat analyses did not show a statistically significant risk reduction in the composite endpoint of recurrent stroke or transient ischemic attack in the transcatheter closure group when compared with medical therapy (RR 0.73, 95% CI 0.45 to 1.17). A time-to-event analysis combining the results of two RCTs also failed to show a significant risk reduction with transcatheter device closure (HR 0.69, 95% CI 0.43 to 1.13).  
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  - Safety analysis found that the overall risks for all-cause mortality and adverse events were similar in both the transcatheter device closure and medical therapy groups; however, transcatheter device closure increased the risk of new-onset atrial fibrillation (RR 3.50, 95% CI 1.47 to 8.35) and may be associated with the type of device used. |
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  - Median age and median weight were 4.0 years (range: 0.3-52.0 years old) and 15.3 kg (range: 4.5-91.0 kg), respectively.  
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  - In summary, 1497 patients underwent transcatheter closure, among which 1492 were successful.  
  - Devices used were Amplatzer duct occluder I (n=1280, 85.8 percent), Cook detachable coils (n=116, 7.8 percent), Amplatzer duct occluder II (n=68, 4.6 percent), muscular VSD occluder (n=12, 0.8 percent), and Amplatzer vascular plug (n=16, 1.0 percent). |
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  - Systematic review assessed clinical outcomes from transcatheter closure in 4406 patients with VSD (perimembranous = 3,758, muscular = 419, intracristal = 47, doubly... |
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- The combined outcome of death, and vascular events, showed a borderline statistically significant benefit for PFO closure when compared to medical treatment, pooled HR = 0.67, 95%CI (0.44-1.00), P = 0.05  
- Subjects with a substantial PFO shunt seem to benefit the most with closure, pooled HR = 0.35, 95%CI (0.12-1.03), P = 0.06, however, it did not reach statistical significance. |
| Riaz (2013) | Key points:  
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- The primary outcome was a composite end-point of death, stroke and transient ischemic attack.  
- Mean follow-up was 2.5 years.  
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- However, the results were statistically significant using per-protocol analysis (HR: 0.64, 95% CI: 0.41 to 0.98; p = 0.043). Males had significant benefit with device closure (HR: 0.48, 95% CI: 0.24 to 0.96; p = 0.038). |
| Law (2009) | Key points:  
- Clinical trial examined transcatheter closure of ASD in patients age ≥2 years, isolated secundum ASD, evidence of right ventricular volume overload, and maximum stretched diameter <22 mm.  
- Clinical success in the trial was defined as complete closure or residual leak ≤2 mm, absence of a severe complication and no need for an additional device or surgery to
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References

Professional society guidelines/other:

None.

Peer-reviewed references:


**CMS National Coverage Determinations (NCDs):**

No NCDs identified as of the writing of this policy.

**Local Coverage Determinations (LCDs):**

No LCDs 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.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comments</th>
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<tbody>
<tr>
<td>93580</td>
<td>Percutaneous transcatheter closure of congenital interatrial communication (ie, Fontan fenestration, atrial septal defect) with implant</td>
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<td>93581</td>
<td>Percutaneous transcatheter closure of a congenital ventricular septal defect with implant</td>
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<tr>
<td>93582</td>
<td>Percutaneous transcatheter closure of patent ductus arteriosus</td>
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<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
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<td>I23.1 - I23.2</td>
<td>Atrial or ventricular septal defect as current complication following acute myocardial infarction</td>
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<td>I51.0</td>
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<td>Q21.0</td>
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<td>Q21.3</td>
<td>Tetralogy of Fallot</td>
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<tr>
<td>Q25.0</td>
<td>Patent ductus arteriosus</td>
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<td>C1817</td>
<td>Septal defect implant system, intracardiac</td>
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