Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 3/1/25**
(See policy history boxes for previous effective dates)

Title: Trans*myocardial* (Perventricular) Closure of Ventricular Septal Defects

Description/Background

Transmyocardial (perventricular) Device Closure

Transmyocardial (perventricular) device closure of a ventricular septal defect (VSD) involves puncturing the wall of the right ventricle and inserting a device between the left and right ventricles in order to repair a septal defect, using an occlusive device. It is performed as part of a combination hybrid procedure which involves standard cardiac surgical techniques for correction of coexisting abnormalities, combined with perventricular intervention for VSD closure. This technique has been investigated as an alternative to percutaneous transcatheter techniques combined with cardiac surgery, for repairing complex congenital cardiac defects that are not readily amenable to more established approaches. Advantages include that the procedure can be performed on a beating heart, cardiopulmonary bypass is avoided, and it can be performed under echocardiographic guidance. Potential complications include creating a residual shunt, causing heart block, valvular injury, embolization, hemolysis, left ventricular trauma, and death.

Ventricular Septal Defect

A VSD is a defect in the wall (septum) between the right and left ventricle. Septal defects are sometimes referred to as a "hole" in the heart. Ventricular septal defects are the most common congenital heart defect in newborns. They are less common in older children and adults.

On rare occasion, a heart attack can lead to interventricular septal defects, which may result in 1 or more of the serious complications listed below. Rupture of the intraventricular septum is an uncommon but often fatal complication of acute MI or traumatic injury.

A VSD opens a port for blood to flow backwards from the left ventricle into the right ventricle, thus providing the lungs with a surplus of blood flow. This overload can ultimately lead to congestive heart failure, pulmonary vascular disease and an increase in the risk of infective endocarditis.

The ventricular septum consists of an inferior muscular and superior membranous portion. The membranous portion, which is close to the atrioventricular node, is most commonly affected in adults and older children in the United States. The membranous type of VSD is the type that most commonly requires surgical intervention. On occasion, the body is able to repair congenital VSDs without surgical intervention.

Management of VSDs is dependent on the size and pathophysiology of the septal defect. A small, asymptomatic defect may not require treatment. Conventional open-heart surgery is generally reserved for those individuals with large defects.

Other Approaches

Percutaneous Transcatheter Closure
Percutaneous transcatheter closure involves introducing a guide wire into the femoral artery. A delivery sheath is advanced over the wire across the defect. Under fluoroscopic guidance, an occluder device is placed and expanded over the defect to close it.

Regulatory Status

The CardioSEAL® Septal Occlusion System with QuikLoad™ (Nitinol Medical Technologies, Inc.) received FDA approval (2001), for use (as a transcatheter cardiac occlusion device) in individuals with complex VSDs of significant size to warrant closure and who are considered at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or overall medical condition.

A modified version of the CardioSEAL device, the STARFlex® Septal Occlusion System, received FDA PMA approval in 2009. The device was indicated for use in individuals with a complex ventricular septal defect of a significant size to warrant closure when, based on location, cannot be closed with standard transatrial or transarterial approaches. (Not FDA approved for Transmyocardial approach). However, NMT Medical, Inc ceased operations in 2011.

The Amplatzer Muscular VSD Occluder received FDA premarket approval in 2007. The device is indicated for use (as a *percutaneous* transcatheter occlusion device) in individuals with a complex VSD of significant size to warrant closure (large volume, left to right shunt, pulmonary hypertension and/or clinical symptoms of congestive heart failure) who are considered to be at high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or based on overall medical condition. The FDA approval for the Amplatzer device lists the same high-risk anatomical factors included in the approval letter for the CardioSEAL Septal Occlusion System with QuikLoad™, listed above. (Not FDA approved as a Transmyocardial device)

In 2017 the Amplatzer Post Infarct Muscular VSD Occluder received Humanitarian Device Exemption approval. The amplatzer post-infarct muscular VSD occluder is a *percutaneous* transcatheter occlusion device intended for closure of post myocardial infarct muscular ventricular septal defects in individuals who are not satisfactory surgical candidates.

At present, no devices are approved by the FDA for use as a trans*myocardial* (perventricular) occlusion device.

Medical Policy Statement

Transmyocardial closure of ventricular septal defects is considered experimental/investigational. The safety and effectiveness have not been established.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

33999

Rationale

The use of a perventricular approach, also referred to as a transmyocardial approach, has been explored as an alternative to the transcatheter approach for ventricular septal defect (VSD) closure. This hybrid approach has been investigated in the treatment of individuals for whom transcatheter closure is challenging, including small infants and individuals with poor vascular access.

Fulton et al (2024; Up-To-Date) reported on the management of isolated ventricular septal defects in infants and children. Surgical interventions for closure of moderate to large ventricular septal defects in individuals who remain symptomatic despite medical therapy include primary patch closure as the preferred procedure in most instances, and transcatheter closure reserved for individuals with defects that are challenging to close operatively or for those who are unable to undergo cardiopulmonary bypass for various reasons. Transmyocardial approaches were not mentioned as a type of surgical option for the closure of VSDs.

Transmyocardial (Perventricular) Transcatheter Closure of Ventricular Septal Defects
Thakkar et al (2012) reported on a study of single center experience of mid-term safety and efficacy of perventricular device closure of isolated large muscular ventricular septal defect (mVSD) in high-risk infants, since surgical closures of large mVSDs in infants represent a challenge with significant morbidity. Between August 2008 and 2010, perventricular closure

was attempted in 24 infants of 6.01 months of age (± 2.37) and a weight of 4.27 kg (± 0.56) under TEE guidance. Results: The device was successfully deployed in 21/24 infants. Size of the mVSD was 8.42 mm (± 1.46) (6.1e12 mm). Mean procedure time was 28.8 min (± 11.7). The closure rate was 84% immediately and 100% at 6 months. Four patients suffered major complications: 2-died, 1-esophageal perforation, 1-persistent complete heart block. At 26.23 months (± 6.63) follow-up, 2 subjects were symptomatic: 1-required device retrieval, 1-died of severe gastroenteritis. The authors concluded that perventricular device closure of isolated mVSD appears feasible option at mid-term follow-up and may either substitute or complement the conventional surgical technique in selected cases depending on institutional pediatric cardiac surgery performance. They also state that the procedural safety can be improved with more precautions for preventable complications. Until specifically designed hardware is available, very large defect or defects extending into inlet, posterior or apical septum are not suitable for perventricular closure.

Hu et al (2013) reported on a study done between April 2010 and July 2013 wherein 463 children with isolated subaortic VSDs were enrolled in a study: percardiac device closure of their VSDs as an alternative to surgical repair in certain subjects. The goals of this study were to compare the percardiac interventional procedure with open-heart surgery and report the short- and medium-term outcomes of 2 different approaches for treating subaortic VSDs. The population to be enrolled was defined as those with subaortic VSDs with a ≤2 mm rim of tissue between the aortic valve and the defect. These individuals were divided into 2 groups according to the parents' choice. In Group A, 161 children underwent an initial attempt at percardiac device closure. In Group B, 302 children underwent a repair procedure under cardiopulmonary bypass. Group A had much lower values of operative time, postoperative mechanical ventilation time, cardiac intensive care unit duration, postoperative hospitalization time and need for blood transfusion than Group B. In Group A, 145 (90.06%) subjects were successfully occluded, whereas 16 (9.94%) individuals were converted to open-heart surgery after occlusion failure. After accounting for numerous variables, the authors concluded that the new percardiac technique may be an alternative to classic surgery for ventricular septal defect. Long-term follow-up is mandatory to assess the safety and effectiveness of this procedure as an alternative to conventional therapy.

Omelchenko et al (2014) described a new technique of perventricular closure of a perimembranous ventricular septal defect on a beating heart using transesophageal echocardiography guidance and video-assisted thoracoscopy. Three individuals were treated with this approach (ages 4, 5, and 6 years; weight, 15 to 17.5 kg, 1 of them had a subaortic VSD and we used an eccentric occluder). The 3-month follow-up examination revealed excellent cosmetic results in all subjects, with no shunts, conduction disturbances, or valve complications in any individual. The authors conclude that this procedure is safe and effective for selected individuals. These early and mid-term results encourage further evaluation. Further studies are warranted for the perventricular closure of VSDs.

Prêtre (2014) admits that while the results of this new method are reassuring on a short-term basis, there are long-term concerns. The interruption of the ventricular septum (a supporting structure) that a transmyocardial approach causes will affect the basic structure and thus the flow of blood. Malalignment of the septum, which occurs during puncturing of the right ventricle, has the potential to cause turbulences. Over time turbulences will create a fibrous membrane and lead to the restriction of motion among other complications. Even if turbulences are not detected post-operatively on the TEE, they have the potential to appear when cardiac

outputs increase, such as is the case in active younger patients. The author posed concerns that with higher cardiac outputs, turbulences will promote the development of a subaortic membrane and the scarring tissue may reach the right coronary leaflet. Until a longer follow-up or dynamic study can be completed, the author recommends abiding by the gold standard.

Huang et al (2018) compared perventricular and percutaneous device closure. A total of 572 subjects with isolated VSD were selected in our hospital between January 2015 and December 2016. Median age and weight were 5 years (1-26 years) and 29 kg (9-55 kg), respectively. The median diameter of VSD was 6.0 mm (5-10 mm). Subjects were divided into 2 groups. In group A, perventricular device closure was performed in 427 individuals; in group B, 145 individuals underwent percutaneous device closure. Four-hundred twelve subjects in group A and 135 subjects in group B underwent successful closure. The total occlusion rate was 98.5% (immediately) and 99.5% (3-month follow-up) in group A, which were not significantly different from those in group B (97.7% and 100%, respectively). Perventricular closure lead to an average of 12.5±8.3 hours of Intensive Care Unit (ICU) stay whereas percutaneous device closure resulted in 0 hours of ICU stay. Overall hospital stay was slightly shorter for percutaneous closure versus perventricular closure (3.1±1.9 days versus 3.8±2.1 days). Authors concluded that the percutaneous procedure has the advantage of less trauma when compared to the perventricular approach. Although the perventricular approach had a shorter operative time.

Hong et al (2019) investigated the safety and efficacy of perventricular device closure of perm membranous VSD. The meta-analysis included 15 studies (n=1368). Median follow-up ranged from 2 months to 5 years. The pooled success rate was 0.95 (I2 = 86.2%, P = 0.000). The most common minor complication was residual shunting (n=95/1368). A total of 80 subjects were converted to conventional surgery due to significant residual shunting (36.4%), mild to significant aortic regurgitation (35.2%), severe arrhythmia (11.4%), failure to establish a path (9.1%), and mild to significant tricuspid regurgitation (8.0%). The pooled rate of severe intraoperative complications was 0.050 (95% CI, 0.028 to 0.071; p=0.000). Authors concluded that perventricular device closure may be a safe and effective alternative to conventional surgery but recommended more detailed observations in larger studies. The meta-analysis was limited by the heterogeneity of the studies, lack of information reported, and lack of randomized controlled studies.

Summary of Evidence
Advantages of the transcatheter approach over conventional surgery include a smaller incision, shorter hospital length of stay, and fewer complications, particularly since cardiopulmonary bypass is not required. Although the hybrid procedure potentially has promise, extreme caution is warranted. The limited amount of supportive studies that are available, evolved from a single institution, contain small case groups, share the same group of investigators, and lack randomization and long-term follow-up. In addition, no devices have received FDA approval for this application. Perventricular closure has not been proven to be better than the gold standard of surgical approach for the closure of VSDs. There is insufficient evidence in published peer-reviewed scientific literature to support the safety and effectiveness of the perventricular/transmyocardial approach to VSD closure.

Government Regulations
National/LCD:

There are no national or local coverage determinations on this topic.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Closure Devices for Patent Foramen Oval and Atrial Septal Defects
- Transcatheter Aortic Valve Implantation for Aortic Stenosis
- Transcatheter Mitral Valve Repair
- Transcatheter Pulmonary Valve Implantation

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 10/2/24, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
3/1/18	12/12/17	12/12/17	Joint policy established
3/1/19	12/11/18		Routine maintenance
3/1/20	12/17/19		Routine maintenance
3/1/21	12/15/20		Routine maintenance
3/1/22	12/14/21		Routine maintenance
3/1/23	12/20/22		Routine maintenance (slp)
3/1/24	12/19/23		Routine maintenance (slp) Vendor Managed: N/A
3/1/25	12/17/24		Routine maintenance (slp) Vendor Managed: N/A

Next Review Date: 4th Qtr, 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: TRANS*MYOCARDIAL* (PERVENTRICULAR) CLOSURE OF VENTRICULAR SEPTAL DEFECTS

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	Refer to the Medicare information under the Government Regulations section of this policy.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.