Corporate Medical Policy

Transcatheter Closure of Ventricular Septal Defects

File Name: transcatheter_closure_of_ventricular_septal_defects
Origination: 1/2007
Last Review: 6/2024

Description of Procedure or Service

A Ventricular Septal Defect (VSD) is the persistence of one or more holes in the wall (septum) that separates the two lower chambers (ventricles) of the heart. 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. It is also the type that will most commonly require surgical intervention, comprising over 80% of cases.

Membranous ventricular septal defects are more common than muscular ventricular septal defects, and are the most common congenital cardiac anomaly. Development of the ventricular septum in the fetus is usually complete after the seventh week of gestation. If the ventricular septum does not form completely, a hole or defect remains.

A VSD allows blood to leak from the left ventricle through to the right ventricle, thereby increasing the flow of blood to the lungs. This can later result in congestive heart failure, pulmonary vascular disease and an increase in the risk of infective endocarditis.

In adults, interventricular septal defects are a rare, but serious complication of heart attacks. These holes are related to the heart attack and are not the result of a birth defect.

Management of VSDs is dependent on the size and pathophysiology of the defect. A small, asymptomatic defect may not require treatment. Conventional open heart surgery is generally reserved for those patients with large defects. It is performed through an incision in the chest and the defect is closed with a patch.

Transcatheter closure involves introducing a guidewire into the femoral artery. A delivery sheath is advanced over the wire across the defect, usually through the right heart system. Under fluoroscopic guidance, an occluder device is placed and expanded like an umbrella to close the defect. Potential advantages of the transcatheter closure over conventional surgery include a smaller incision, shorter hospital stay and fewer complications, particularly those associated with cardiopulmonary bypass.

Transmyocardial (perventricular) device closure of a VSD approaches the defect by puncturing the wall of the right ventricle, rather than via a percutaneous approach. It is generally performed as part of a combination "hybrid" procedure, which involves standard cardiac surgical techniques for correction of coexisting abnormalities, combined with a perventricular intervention for VSD closure. The technique has been investigated as an alternative to percutaneous transcatheter techniques combined with cardiac surgery, for use in the repair of complex congenital cardiac defects that are not readily amenable to more established approaches.

Regulatory Status

The CardioSEAL® Septal Occlusion System with QuikLoad™ received FDA approval on December 5, 2001, for use in patients 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. According to the FDA approval order, high-risk anatomical factors for transatrial or transarterial surgical closure include:

- patients requiring a left ventriculotomy or an extensive right ventriculotomy
- patients with a failed previous VSD closure
- patients with multiple apical and/or anterior muscular VSDs ("Swiss cheese septum")
- patients with posterior apical VSDs covered by trabeculae

A modified version of the CardioSEAL device, named STARFlex® Septal Occlusion System, received FDA PMA approval on March 5, 2009. The device is indicated for use in patients with a complex ventricular septal defect of a significant size to warrant closure but that, based on location, cannot be closed with standard transatrial or transarterial approaches.

The Amplatzer Muscular VSD Occluder received FDA approval through the PMA process on September 7, 2007. The device is indicated for use in patients 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.

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for transcatheter closure of ventricular septal defects when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

BCBSNC will not provide coverage for transmyocardial (perventricular) closure of ventricular septal defects. It is considered investigational and BCBSNC does not cover investigational services.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Transcatheter Closure of Ventricular Septal Defects is covered

Transcatheter closure, using a Food and Drug Administration (FDA)-approved device, is considered medically necessary for patients with a complex ventricular septal defect of significant size to warrant closure 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.

High risk anatomical factors for transatrial or transarterial surgical closure include individuals:

- requiring a left ventriculotomy or an extensive right ventriculotomy;
- with a failed previous VSD closure;
- with multiple apical and/or anterior muscular VSDs ("Swiss Cheese Septum"); or
- with posterior apical VSD covered by trabeculae.

When Transcatheter Closure of Ventricular Septal Defects is not covered

Transcatheter closure of VSD for any indication not listed above is considered investigational.

Use of non-FDA approved devices is considered investigational.

In addition, trancatheter closure of VSD is contraindicated in individuals with the following:

- thrombus at or near the intended site of implant, or documented evidence of venous thrombus in the vessels through which access to the defect is gained unless the individual is protected with other embolic protection devices such as a vena cava filter,
- active endocarditis, or other infections producing bacteremia,
- vasculature inadequate to accommodate the delivery system,
- a defect too small to allow the access system to cross the defect,
- anatomy in which the device delivery system would interfere with other intracardiac or intravascular structures, such as valves or pulmonary veins,
- inability to take aspirin, heparin, coumadin, or other anticoagulants.

Transmyocardial (perventricular) transcatheter closure of ventricular septal defects with implants is considered investigational.

Policy Guidelines

This policy was updated with a literature search through May 2018. There is sufficient evidence to demonstrate that the transcatheter closure technique is a reasonable alternative for carefully selected patients with a ventricular septal defect of significant size to warrant closure and who are considered to be at high risk for standard transatrial or transarterial surgical closure. Long-term outcome data for transcatheter closure of VSDs is needed prior to broader application of this technique.

There is insufficient evidence in the published medical literature to demonstrate the safety and efficacy of transmyocardial (perventricular) closure of VSD as compared to conventional treatment options. The available literature on this technique is very limited. Very small numbers of cases were reported, mostly by the same group of investigators and involved a single institution. These case reports were also limited by short follow-up periods and lack of randomization. In addition, no devices have received FDA approval for this application.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: *33681, 93581, 33999*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health. CardioSEAL® Septal Occlusion System. P000049. December 5, 2001. http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm083993.htm

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National Institute for Health and Clinical Excellence (NICE). Endovasular closure of perimembranous ventricular septal defect. Interventional Procedure Guidance 172. London, UK: NICE; May 2006. Retrieved 11/21/06 from http://www.nice.org.uk/download.aspx?o=IPG172guidance

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U.S. Food and Drug Administration (FDA), STARFlex® Septal Occlusion System .P000049/S016. March 5, 2009. Retrieved May 18, 2012 from http://www.accessdata.fda.gov/cdrh_docs/pdf/P000049a.pdf

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Yang J, Lifong Y, Wan Y, et al. Transcatheter device closure of perimembranous ventricular septal defects: mid-term outcomes. Eur Heart J. 2010 September; 31(18): 2238–2245. Retrieved from http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2938468/

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Warnes CA, Williams RG, Bashore TM, Child JS, Connolly HM, Dearani JA et al. ACC/AHA 2008 guidelines for the management of adults with congenital heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Develop Guidelines on the Management of Adults With Congenital Heart

Disease). Developed in Collaboration With the American Society of Echocardiography, Heart Rhythm Society, International Society for Adult Congenital Heart Disease, Society for Cardiovascular Angiography and Interventions, and Society of Thoracic Surgeons. J Am Coll Cardiol. 2008 Dec 2;52(23):e143-263. doi: 10.1016/j.jacc.2008.10.001.

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Ergene O, Kahya Eren N., Nazli C, Duygu H, Kocabas U. Percutaneous closure of perimembranous ventricular septal defects associated with septal aneurysm in adults. Turk Kardiyol Dern Ars. 2015 Dec; 43 (8):699-74. Doi: 10.5543/tkda.2015.50945.

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Specialty Matched Consultant Advisory Panel review 6/2022

Medical Director review 6/2022

Specialty Matched Consultant Advisory Panel review 6/2023

Medical Director review 6/2023

Specialty Matched Consultant Advisory Panel review 6/2024

Medical Director review 6/2024

Policy Implementation/Update Information

1/29/07 New policy issued. Transcatheter closure is considered medically necessary for patients with a complex ventricular septal defect of significant size to warrant closure 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. Transcatheter closure of VSD for any other indication is considered investigational. (adn)

11/19/07 Specialty Matched Consultant Advisory Panel review 10/29/07. Policy accepted as written. (adn)

12/7/09 Added the following policy statement: "BCBSNC will not provide coverage for transmyocardial/perventricular closure of ventricular septal defects. It is considered investigational and BCBSNC does not cover investigational services." Description of transmyocardial/perventricular closure added to Description Section. The following statement added to the Not Covered section: Transmyocardial (perventricular) transcatheter closure of ventricular septal defects with implants is considered investigational. Information added to Policy Guidelines section. Specialty Matched Consultant Advisory Panel review meeting 10/30/09. Notification 12/7/09 for effective date 3/16/10. (adn)

11/26/10 Specialty Matched Consultant Advisory Panel review 6/2010. Removed Medical Policy number. Removed “VSD acquired post myocardial infarction” from the section titled, “When Transcatheter Closure of Ventricular Septal Defects is not Covered”. Updated references. (mco)

7/19/11 Specialty Matched Consultant Advisory Panel review 6/2011. No changes to policy statements. (mco)

12/30/11 Deleted codes 0166T and 0167T from “Billing/Coding” section. Added code 33999. (mco)

7/10/12 Description section updated to include regulatory status of available FDA approved devices. References updated. Specialty Matched Consultant Advisory Panel review 6/2012. (mco)

7/16/13 References updated. Specialty Matched Consultant Advisory Panel review 6/2013. Medical Director review 6/2013. (mco)

7/15/14 Description section updated. Added the following statement to the “When not Covered” section : “Use of non-FDA approved devices is considered investigational.” References updated. Specialty Matched Consultant Advisory Panel review 6/2014. Medical Director review 6/2014. (mco)

9/1/15 Specialty Matched Consultant Advisory Panel review 6/24/2015. Medical Director review 6/2015. Policy Statement unchanged. (td)

7/26/16 References updated. Specialty Matched Consultant Advisory Panel review 6/2016. Medical Director review 6/2016. (jd)

7/28/17 Specialty Matched Consultant Advisory Panel review 6/2017. Medical Director review 6.2017. (jd)

7/27/18 Specialty Matched Consultant Advisory Panel review 6/2018. Medical Director review 6/2018. (jd)

7/1/19	Specialty Matched Consultant Advisory Panel review 6/2019. Medical Director review 6/2019. (jd)
6/30/20	Specialty Matched Consultant Advisory Panel review 6/2020. Medical Director review 6/2020. (jd)
7/1/21	Specialty Matched Consultant Advisory Panel review 6/2021. Medical Director review 6/2021. (jd)
7/12/22	Specialty Matched Consultant Advisory Panel review 6/2022. Medical Director review 6/2022. (jd)
6/30/23	References updated. Specialty Matched Consultant Advisory Panel review 6/2023. Medical Director review 6/2023. (tm)
7/17/24	References updated. Specialty Matched Consultant Advisory Panel review 6/2024. Medical Director review 6/2024. (tm)