

## Corporate Medical Policy

### Transcatheter Closure of Ventricular Septal Defects

**File Name:** transcatheter\_closure\_of\_ventricular\_septal\_defects  
**Origination:** 1/2007  
**Last CAP Review:** 6/2011  
**Next CAP Review:** 6/2012  
**Last Review:** 6/2011

#### Description of Procedure or Service

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A Ventricular Septal Defect (VSD) is the persistence of one or more holes in the muscular wall (septum) that separates the two lower chambers (ventricles) of the heart. VSD is one of the most common congenital heart defects. 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.

**\*\*\*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

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**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**

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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

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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

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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.

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

- 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

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

In addition, transcatheter closure of VSD is contraindicated in patients 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 patient 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

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considered investigational.

## Policy Guidelines

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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 (periventricular) 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

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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](http://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

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U.S. Food and Drug Administration (FDA), Center for Devices and Radiological Health. CardioSEAL® Septal Occlusion System. P000049. December 5, 2001. Retrieved 11/21/06 from <http://www.fda.gov/cdrh/mda/docs/p000049.html>

Holzer R, Balzer D, Cao Q, Lock K, Hijazi ZM. (October 2003). Device Closure of Muscular Ventricular Septal Defects Using the Amplatzer Muscular Ventricular Septal Defect Occluder. *J Am Coll Cardiol* 2004;43:1257-63.

National Institute for Health and Clinical Excellence (NICE). Endovascular 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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Bacha EA, Hijazi ZM, Cao QL, Abdulla R, Starr JP, Quinones J, et al. (2005). Hybrid pediatric cardiac surgery. *Pediatr Cardiol*. 2005c Jul-Aug;26(4):315-22

National Institute for Clinical Excellence (NICE). Transcatheter Endovascular Closure of

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Perimembranous Septal Defect. Interventional Procedure Guidance 336. London, UK: NICE; March 2010. Retrieved 4/27/10 from <http://guidance.nice.org.uk/IPG336>

Specialty Matched Consultant Advisory Panel 6/2011

## 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)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.