

**Policy terminated because Medicaid covers codes in the same manner as
Health Choice.**

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1.0 Description of the Procedure, Product, or Service

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 do not result from 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 recipients with large defects. It is performed through an incision in the chest and the defect 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.

2.0 Eligible Recipients

2.1 General Provisions

To be eligible, NCHC recipients must be enrolled on the date of service.

3.0 When the Procedure, Product, or Service Is Covered

3.1 General Criteria

NCHC covers procedures, products, and services related to this policy when they are medically necessary and

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the recipient's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available; **AND**
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

3.2 Specific Criteria

Transcatheter closure of ventricular septal defects is covered under the NC Health Choice Program when it is determined to be medically necessary for recipients with a complex 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 based on anatomical conditions and/or based on overall medical condition.

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

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

3.3 Policy Guidelines

There is sufficient evidence to demonstrate that the transcatheter closure technique is a reasonable alternative for carefully selected recipients 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.

4.0 When the Procedure, Product, or Service Is Not Covered

4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental or investigational.

4.2 Specific Criteria

Transcatheter closure of VSD is not covered in the following situations:

- a. Transcatheter closure of VSD for any indication not listed in **Subsection 3.2** is considered investigational.
- b. Transcatheter closure of VSD is contraindicated in recipients with the following:
 1. 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 recipient is protected with other embolic protection devices such as a vena cava filter,
 2. active endocarditis, or other infections producing bacteremia,
 3. vasculature inadequate to accommodate the delivery system,
 4. a defect too small to allow the access system to cross the defect,
 5. anatomy in which the device delivery system would interfere with other intracardiac or intravascular structures, such as valves or pulmonary veins,
 6. inability to take aspirin, heparin, coumadin, or other anticoagulants,
 7. VSDs acquired post myocardial infarction.
- c. Transmyocardial (perventricular) transcatheter closure of ventricular septal defects is not covered under the NC Health Choice Program. It is considered investigational and the NC Health Choice Program does not cover investigational services.

4.3 Policy Guidelines

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.

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval

Prior approval is not required for transcatheter closure of ventricular septal defects.

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **AND**

- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

7.0 Additional Requirements

7.1 Compliance

Providers must comply with all applicable federal, state, and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

8.0 Policy Implementation/Revision Information

Original Effective Date: July 1, 2010

Revision Information:

Date	Section Revised	Change
July 1, 2010	Throughout	Policy Conversion; Implementation of Session Law 2009-451, Section 10.32 “NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY.”
February 29, 2012	Throughout	Policy Termination

Attachment A: Claims-Related Information

Reimbursement for transcatheter closure of ventricular septal defects requires compliance with all NCHC guidelines. As transmyocardial (periventricular) transcatheter closure of ventricular septal defects is non-covered, claims-related information is not applicable.

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

B. Diagnosis Codes

Providers must bill the ICD-9-CM diagnosis codes(s) to the highest level of specificity that supports medical necessity.

C. Procedure Code(s)

CPT Codes
33681
93581

D. Modifiers

Providers are required to follow applicable modifier guidelines.

E. Billing Units

The appropriate procedure code(s) used determines the billing unit(s).

F. Place of Service

Inpatient Hospital

G. Co-payments

Co-payment(s) may apply to covered prescriptions and services.

H. Reimbursement

Providers must bill their usual and customary charges