Transcatheter Closure Devices for Septal Defects

Policy ID:	HHO-DE-MP-1234
Approved By:	Highmark Health Options – Market Leadership
Provider Notice Date:	12/15/2021; 03/01/2023
Original Effective Date:	01/15/2022; 04/01/2023
Annual Approval Date:	12/28/2022
Last Revision Date:	12/22/2021; 12/28/2022
Products:	Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 5

Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under medical surgical benefits of the Company's Medicaid products for medically necessary transcatheter closure devices for septal defects.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children (DHCP) and Diamond State Health Plan Plus members.

Transcatheter Percutaneous Cardiac Occlusion Devices – Are for use in minimally invasive repair of cardiac septal defects. These defects can be congenital or acquired. These devices offer an alternative to conventional open-heart surgery.

PROCEDURES

A prior authorization is required.

A U.S. Food and Drug Administration (FDA) approved percutaneous septal occlusion device used according to labeling, may be considered medically necessary for ANY following cardiac septal defects:

- Closure of a secundum atrial septal defect (ASD); or
- Closure of a fenestrated septal opening as a result of the Fontan procedure; or
- Closure of a patent ductus arteriosus (PDA); or
- Closure of a complex ventricular septal defect (VSD); or
- For individuals that are considered high risk for standard transarterial or transarterial surgical VSD closure due to anatomic conditions and overall medical condition; or
- Closure of surgical shunts or collaterals.

A percutaneous septal occlusion device is contraindicated for use in individuals with ANY of the following:

- Known to have local or generalized sepsis, or any systemic infection that cannot be successfully treated within one (1) month prior to device placement; or
- Whose size or condition would cause the individual to be a poor candidate for cardiac catheterization; or
- With the margins of the defect less than five (5) mm to the coronary sinus, AV valves and right upper lobe pulmonary vein; or
- With 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; or
- Whose anatomy would interfere with other intracardiac or intravascular structures, such as valves or pulmonary veins should a septal occlude be used; or
- With an intra-cardiac mass or vegetation; or
- Unable to take anti-platelet or anticoagulant medications such as aspirin, heparin, or warfarin, successfully prior to device placement; or
- Whose vasculature is inadequate to accommodate a septal occlusion device.

All other devices or uses are considered experimental and investigational and, therefore, non-covered because the safety and/or effectiveness of this service cannot be established by the available published peer-review literature.

Transcatheter closure of patent foramen ovale (PFO) with an FDA approved device may be considered medically necessary in individuals 18 years of age or older, with a history of ischemic stroke presumed to be secondary to a paradoxical embolism, following a negative workup for other causes of ischemic stroke.
All other devices or uses are considered experimental and investigational and, therefore, non-covered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

POST-PAYMENT AUDIT STATEMENT

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

PLACE OF SERVICE: INPATIENT

Experimental/investigational (E/I) services are not covered regardless of place of service.

CODING REQUIREMENTS

CPT code	Description
93580	Percutaneous transcatheter closure of congenital interatrial communication (i.e., Fontan fenestration, atrial septal defect) with implant.
93581	Percutaneous transcatheter closure of congenital ventricular septal defect with implant.

93582	Percutaneous transcatheter closure of patent ductus arteriosus.

COVERED DIAGNOSIS CODES FOR PROCEDURE CODES: 93580, 93581 AND 93582

Codes						
I23.1	I23.2	I51.0	Q21.0	Q21.10	Q21.11	Q21.12
Q21.13	Q21.14	Q21.15	Q21.16	Q21.19	Q21.20	Q21.21
Q21.22	Q21.23	Q21.3	Q21.9	Q25.0		

PROFESSIONAL STATEMENTS AND SOCIETAL POSITIONS GUIDELINES

American College of Cardiology and American Heart Association-2018
The American College of Cardiology and American Heart Association updated guidelines on the management of adults with congenital heart disease. The treatment recommendations are summarized in the table below. However, for coronary sinus or primum atrial septal defects, surgery, rather than percutaneous closure, was recommended.

TABLE

Condition	Recommendation	COR[a]/LOE[b]
Symptomatic isolated secundum ASD, right atrial and/or RV enlargement, and net left-to-right shunt sufficiency large enough to cause physiological sequelae, without cyanosis at rest or during exercise.	Transcatheter or surgical closure	I1/B-NR2
Symptomatic primum ASD, sinus venosus defect, or coronary sinus defect, right atrial and/or RV enlargement, and net left-to-right shunt sufficiency large enough to cause physiological sequelae, without cyanosis at rest or during exercise.	Surgical closure unless precluded by comorbidities	I1/B-NR2
Asymptomatic isolated secundum ASD, right atrial and RV enlargement, and net left-to-right shunt sufficiency large enough to cause physiological sequelae, without cyanosis at rest or during exercise.	Transcatheter or surgical closure	IIa1/C-LD2
Secundum ASD when a concomitant surgical procedure is being performed and there is a net left-to-right shunt sufficiently large enough to cause physiological sequelae, and right atrial and RV enlargement without cyanosis at rest or during exercise.	Surgical closure	IIa1/C-LD2
ASD when net left-to-right shunt is ≥1.5:1, PA systolic pressure and/or pulmonary vascular resistance is greater than of one-third of systemic resistance.	Percutaneous or surgical closure	IIb1/B-NR2
ASD with PA systolic pressure greater than two-thirds systemic, pulmonary vascular resistance greater than two-thirds systemic, and/or a net left-to-right shunt.	ASD closure should not be performed	III-Harm1/C-LD2

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

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POLICY UPDATE HISTORY

12/22/2021	Approved in Medical Policy Committee
01/2022	Approved in QI/UM
12/28/2022	Annual review; approved in Medical Policy Committee
01/03/2023	Approved in QI/UM