NO. 91528

TRANSCATHETER CLOSURE OF SEPTAL DEFECTS

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Instructions for use: This document is for informational purposes only. Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable. Eligibility and benefit coverage are determined in accordance with the terms of the member's plan in effect as of the date services are rendered. It is not an authorization, certification, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of coverage. Priority Health's medical policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Priority Health reserves the right to review and update its medical policies at its discretion. Priority Health's medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan's ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.

Policy scope: This medical policy addresses the percutaneous transcatheter closure of septal defects.

Related policies: None identified.

I. MEDICAL NECESSITY CRITERIA

A. Atrial septal defects:

1. **INCLUSIONS**: Percutaneous transcatheter closure of congenital atrial septal defect is considered medically necessary when the following InterQual® criteria have been met:

   CP:Procedures
   Subset: *Atrial Septal Defect (ASD) Repair*
   Requested Service: Arial Septal Defect (ASD) Repair, Percutaneous

2. **LIMITATIONS:** Percutaneous transcatheter closure of congenital atrial septal defect is considered NOT medically necessary when InterQual® criteria have been NOT been met.

B. **Non-atrial septal defects**. Transcatheter closure of non-atrial septal defects using FDA approved devices may be considered medically necessary for any of the following:

1. Patent ductus arteriosis (PDA)
2. Fenestration following a Fontan procedure
3. Ventricular septal defects

C. **EXCLUSIONS**: Transcatheter closure of septal defects is considered not medically necessary for all other indications including, but not limited to

1. Presence of any of the following conditions:

a. Severe pulmonary artery hypertension
b. Right to left shunt
c. Ostium primum, sinus venosus, or coronary sinus ASD
d. Extensive congenital cardiac anomalies which can only be repaired by open cardiac surgery
e. Inability to take antiplatelet or anticoagulant preventative medications (e.g., aspirin, heparin, warfarin)
f. Intracardiac thrombi on echocardiography
g. Patient vasculature too small to accommodate the catheter delivery system
h. Any condition that would contraindicate cardiac catheterization (e.g., infection, sepsis)
i. Location of defect would cause device to interfere with intracardiac or intravascular structures (e.g., cardiac valves, coronary sinus, pulmonary veins)

2. Migraine prophylaxis
3. Transmyocardial (perventricular) transcatheter closure of ventricular septal defects
4. Obstructive sleep apnea

II. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the CMS Online Manual System (IOMs) and Transmittals.
For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to CMS Medicare Coverage Database.

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the

most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare Coverage Database website for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

National Coverage Determinations (NCDs)	
None identified	
Local Coverage Determinations (LCDs)	
CGS Administrators, LLC	None identified
First Coast Service Options, Inc.	None identified
National Government Services, Inc.	None identified
Noridian Healthcare Solutions	None identified
Novitas Solutions, Inc.	None identified
Palmetto GBA	None identified
WPS Insurance Corporation	None identified

III. BACKGROUND

An atrial septal defect is a congenital anomaly where a hole in the septum separating the left and right atria results in increased blood flow to the lungs. Transcatheter septal occlusion devices are implantable devices that are used to repair septal wall defects. Atrial or ventricular defects in the septal wall of the heart can have a number of adverse consequences, including abnormal ventricular volume load, ventricular pressure load, mixing of unoxygenated and oxygenated blood and inadequate systemic cardiac output. These abnormalities can lead to cardiac enlargement, pulmonary hypertension, rhythm disturbance, and stroke.

Conventional open-heart surgical repair of septal defects carries some risk, especially in patients in whom heart or pulmonary function may be compromised. In addition, there is considerable morbidity associated with open-heart surgery. Moreover, some types of ventricular septal defects (VSDs) are difficult to repair surgically due to their location or orientation. Consequently, there has been considerable interest in the development of a transcatheter method of repairing septal lesions. Access to the defect is achieved through the venous system via the internal jugular vein or femoral vein in the groin.

Severe pulmonary artery (PA) hypertension is a contraindication to closure and should be accurately assessed and treated prior to repair. Testing for PA hypertension is part of the preoperative evaluation to determine suitability for atrial septal defect (ASD) repair. Guidelines from the American Heart Association and the American College of Cardiology recommend against ASD closure with a PA systolic pressure greater than two thirds systemic or pulmonary vascular resistance greater than two thirds systemic because they are associated with higher morbidity and mortality with surgical repair.

InterQual® Procedures criteria are derived from the systematic, continuous review and critical appraisal of the most current evidence-based literature and include input from our independent panel of clinical experts. To generate the most appropriate recommendations, a comprehensive literature review of the clinical evidence was conducted. Sources searched included PubMed, Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Reviews, the Cochrane Library, Centers for

Medicare & Medicaid Services (CMS) National Coverage Determinations, and the National Institute for Health and Care Excellence (NICE). Other medical literature databases, medical content providers, data sources, regulatory body websites, and specialty society resources may also have been used. Relevant studies were assessed for risk of bias following principles described in the Cochrane Handbook. The resulting evidence was assessed for consistency, directness, precision, effect size, and publication bias. Observational trials were also evaluated for the presence of a dose-response gradient and the likely effect of plausible confounders.

IV. GUIDELINES / POSITION STATEMENTS

Medical/Professional Society	Guideline
American College of Cardiology / American Heart Association	2025 ACC/AHA/HRS/ISACHD/SCAI Guideline for the Management of Adults With Congenital Heart Disease: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines (Writing Committee Members; Gurvitz M et al., 2026)
Society for Cardiovascular Angiography and Interventions (SCAI)	SCAI Guidelines for the Management of Patent Foramen Ovale (Kavinsky et al., 2022) Guidelines for the Echocardiographic Assessment of Atrial Septal Defect and Patent Foramen Ovale: From the American Society of Echocardiography and Society for Cardiac Angiography and Interventions (Silvestry FE et al., 2015)
European Society of Cardiology	Ventricular septal defect complicating acute myocardial infarction: diagnosis and management. A Clinical Consensus Statement of the Association for Acute CardioVascular Care (ACVC) of the ESC, the European Association of Percutaneous Cardiovascular Interventions (EAPCI) of the ESC and the ESC Working Group on Cardiovascular Surgery (Schlotter F et al., 2024) 2020 ESC Guidelines for the management of adult congenital heart disease (Baumgartner H et al., 2021)

V. REGULATORY (US FOOD AND DRUG ADMINISTRATION)

See U.S. Food & Drug Administration (FDA) Medical Device Databases for the most current information.

For transcatheter septal defect closure, FDA relies on Class III cardiovascular device product codes. The core product codes are:

OZG – Transcatheter Septal Occluder (Atrial)

MLV – Transcatheter Septal Occluder

All are Class III devices requiring PMA, and all correspond to permanently implanted cardiac occlusion devices.

Device	Premarket Approval, 513(f)(2)(De Novo), or 510(k) Number	Decision date
OZG – Transcatheter Septal Occluder (Atrial)		
Occlutech® ASD Occluder and Occlutech® Pistol Pusher (Occlutech Holding AG)	P200032	12/29/2023
MLV – Transcatheter Septal Occluder		
AMPLATZER PFO OCCLUDER (ABBOTT MEDICAL)	P120021	11/01/2016
GORE HELEX SEPTAL OCCLUDER (W. L. Gore & Associates, Inc.)	P050006	08/11/2006
AMPLATZER MUSCULAR VSD OCCLUDER (ABBOTT MEDICAL)	P040040	09/07/2007
CARDIOSEAL SEPTAL OCCLUSION SYSTEM WITH QWIKLOAD (Nmt Medical, Inc.)	P000049	12/05/2001
THE AMPLATZER(R) SEPTAL OCCLUDER (ASO) AND THE AMPLATZER EXCHANGE SYSTEM (ABBOTT MEDICAL)	P000039	12/05/2001

VI. CODING

ICD-10 Codes that may support medical necessity

G45.0 – G45.9	Transient cerebral ischemic attacks and related syndromes
I23.1	Atrial septal defect as current complication following acute myocardial infarction
I51.0	Cardiac septal defect, acquired
I63.9	Cerebral infarction, unspecified
Q21.10-Q21.19	Atrial septal defect
Q21.20-Q21.23	Atrioventricular septal defect
Q25.0	Patent ductus arteriosus

CPT/HCPCS Codes

93580 Percutaneous transcatheter closure of congenital interatrial communication (i.e., Fontan fenestration, atrial septal defect) with implant
93582 Percutaneous transcatheter closure of patent ductus arteriosus

C1817 Septal defect implant system, intracardiac
C2628 Catheter, occlusion

Not Covered
93581 Percutaneous transcatheter closure of a congenital ventricular septal defect with implant
93799 Unlisted cardiovascular service or procedure *(for transcatheter ventricular septal defect procedure – explanatory notes must accompany claim)*

VII. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, devices, services and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service or procedure is medically necessary. For more information, refer to the Priority Health Provider Manual.

Individual case review may allow coverage for care or treatment that is investigational yet promising for the conditions described. Requests for individual consideration require prior plan approval. All determinations of coverage for experimental, investigational, or unproven treatment will be made by a Priority Health medical director or clinical pharmacist. The exclusion of coverage for experimental, investigational, or unproven treatment may be reviewed for exception if the condition is either a terminal illness, or a chronic, life threatening, severely disabling disease that is causing serious clinical deterioration.

VIII. APPLICATION TO PRODUCTS

Coverage is subject to the member's specific benefits. Group-specific policy will supersede this policy when applicable.

- **HMO/EPO**: This policy applies to insured HMO/EPO plans.
- **POS**: This policy applies to insured POS plans.
- **PPO**: This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- **ASO**: For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.
- **INDIVIDUAL**: For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- **MEDICARE**: Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.
- **MEDICAID/HEALTHY MICHIGAN PLAN**: For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual, the Michigan Medicaid Provider Manual will govern. If there is a

discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

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SUMMARY OF CHANGES

Changes:

- Percutaneous transcatheter closure of congenital atrial septal defect is considered medically necessary when InterQual® criteria have been met

Clarifications:

- Clarified exclusions to transcatheter closure of septal defects

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