Medica Central Coverage Policy

Policy Name:	**Transcatheter Closure of Cardiac Defects MP9625**
Effective Date:	**06/01/2024**

Important Information – Please Read Before Using This Policy
These services may or may not be covered by all Medica Central plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Provider Service Center. Please use the Quick Reference Guide on the Provider Communications page for the appropriate phone number. https://mo-central.medica.com/Providers/SSM-employee-health-plan-for-IL-MO-OK-providers

Medica Central coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

Coverage Policy

Note: This policy is no longer scheduled for routine review of the scientific literature.

Transcatheter closure of atrial septal defect (ASD), ventricular septal defect (VSD), patent ductus arteriosus (PDA), and patent foramen ovale (PFO) is **COVERED** when:

a. The device has received FDA approval, and
b. The FDA-approved indications for the specific device are met.

All other devices and indications, including but not limited to off-label use of FDA approved devices, are investigative and unproven and therefore **NOT COVERED**. There is insufficient reliable evidence in the form of high-quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

Note: The FDA has granted a humanitarian device exemption (HDE) for certain cardiac transcatheter closure devices. Dean Health Plan considers an FDA-approved HDE device medically necessary when all of the FDA-required criteria are met. For a current list of HDE-approved devices, refer to the FDA HDE Database at: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals/ucm161827.htm

Description

Transcatheter closure devices are permanent implantable devices designed to close defects between the chambers of the heart or a patent ductus arteriosus. Most of these

defects are congenital but can occur after a myocardial infarction or can result from surgical repair of other congenital heart defects (e.g. fenestrated Fontan). Developed as less invasive alternatives to open heart surgery, the devices are implanted in a cardiac catheterization laboratory through catheters inserted into a leg vein and advanced to the heart where the device is implanted into the defect.

FDA Approval

Transcatheter closure devices require FDA pre-market approval. Examples of FDA approved devices include, but are not limited to:

A. Amplatzer PFO Occluder (St. Jude Medical, Plymouth, MN), approved on October 28, 2016 for closure of PFO to reduce the risk of recurrent ischemic stroke in patients, predominantly between the ages of 18 and 60 years, who have had a cryptogenic stroke due to a presumed paradoxical embolism, as determined by a neurologist and cardiologist following an evaluation to exclude known causes of ischemic stroke.

B. The Amplatzer® Septal Occluder (ASO) and the Amplatzer® Exchange System (AGA Medical Corp., Golden Valley, MN), approved in December 2001 for the occlusion of ASD in the secundum position and in patients who require closure of a fenestration following a fenestrated Fontan procedure.

C. Amplatzer® Duct Occluder (AGA Medical Corp., Golden Valley, MN) approved in May 2003 for the non-surgical closure of PDA (AGA Medical Corp., Golden Valley, MN).

D. Amplatzer® Multi-Fenestrated Septal Occluder (AGA Medical Corp., Golden Valley, MN). Approved September 2006 for closure of multi-fenestrated (cribriform) atrial septal defects.

E. Amplatzer® Muscular VSD Occluder (AGA Medical Corp., Golden Valley, MN). Approved September 2007 for closure of complex ventricular septal defects of a sufficient size to warrant closure. The patient must also be considered at high risk for surgical closure based either on the anatomy of the defect or the patient's overall medical condition.

F. Amplatzer® Piccolo Occluder (AGA medical Corp., Golden Valley, MN) approved January 2019 as a PMA supplement based on original PMA for Amplatzer® Duct Occluder.

G. CardioSEAL® Septal Occlusion System with Qwik Load™ (NMT Medical, Boston, MA), approved in December 2001 for use in patients with complex ventricular septal defects (VSD) of significant size to warrant closure and who are considered to be high risk for standard transatrial or transarterial surgical closure based on anatomical conditions and/or 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 VSDs covered by trabeculae.

H. GORE HELEX™ Septal Occluder (W.L. Gore & Associates, Inc., Flagstaff, AZ) approved in August 2006 for percutaneous, transcatheter closure of ostium secundum ASDs.

I. Nit-Occlud® PDA (pfm medical, Inc., Carlsbad, CA) approved on August 16, 2013 for percutaneous transcatheter closure of small to moderate size PDA with a minimum angiographic diameter less than 4 millimeters.

J. Starflex Septal Occluder (NMT Medical, Inc., Boston, MA), approved in March 2009 for use in patients with 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. This device replaces the CardioSEAL Septal Occlusion System above.

K. GORE® CARDIOFORM Septal Occluder (W.L. Core & Associates, Inc., Flagstaff, AZ) approved in April 2015 as an addition to the GORE HELEX Septal Occluder Line for closure of ostium secundum atrial septal defects. Expanded approved in March 2018 for closure of PFO to reduce the risk of recurrent ischemic stroke in patients, predominantly between the ages of 18 and 60 years, who have had a cryptogenic stroke due to a presumed paradoxical embolism, as determined by a neurologist and cardiologist following an evaluation to exclude known causes of ischemic stroke.

Prior Authorization

Services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met.

Coding Considerations

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes

- **93580** - Percutaneous transcatheter closure of congenital interatrial communication (ie, Fontan fenestration, atrial septal defect) with implant
- **93581** - Percutaneous transcatheter closure of a congenital ventricular septal defect with implant
- **93582** - Percutaneous transcatheter closure of patent ductus arteriosus

HCPC Code:

- **C1817** - Septal defect implant system, intracardiac

Original Effective Date:	Created 01/18/2023
Re-Review Date(s):	01/17/2024, 05/15/2024
Administrative Update:	05/15/2024