Closure Devices for Patent Foramen Ovale and Atrial Septal Defects

Policy Number:	**M101130045**
Effective Date:	**1/1/2011**
Sponsoring Department:	**Health Care Services**
Impacted Department(s):	**Health Care Services**

Type of Policy: ☒ Internal ☒ External

Data Classification: ☐Confidential ☐Restricted ☒Public

Applies to (Line of Business):

☐ Corporate (All)
☒ State Products, if yes which plan(s): ☒MediSource; ☒ MediSource Connect; ☒Child Health Plus ☒ Essential Plan
☒ Medicare, if yes, which plan(s): ☒MAPD; ☐PDP; ☒ISNP; ☒CSNP
☒ Commercial, if yes, which type: ☒Large Group; ☒Small Group; ☒Individual
☒ Self-Funded Services *(Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.)*

Excluded Products within the Selected Lines of Business (LOB)

N/A

Applicable to Vendors? Yes ☐ No☒

Purpose and Applicability:

To set forth clinical coverage guidelines for closure devices for patent foramen ovale and atrial septal defects.

Policy:

Commercial, Self-Funded and Medicare Advantage:

Patent Foramen Ovale (PFO):
Independent Health considers transcatheter closure of a patent foramen ovale (PFO) using a U.S. Food and Drug Administration (FDA) approved device approved medically necessary for the following indications:

- The prevention of subsequent stroke in individuals with a history of cryptogenic stroke who have failed conventional drug therapy, (for example, warfarin), or who are not candidates for conventional drug therapy; or
- In individuals with a history of cryptogenic stroke who are under age 60 and either:
    a) have an atrial septal aneurysm or
    b) have grade 3 or 4 interatrial shunting.

Atrial Septal Defects (ASD):
Independent Health considers percutaneous transcatheter closure of atrial septal defects (ASDs) using FDA approved closure devices medically necessary for the following indications:

- Those with echocardiographic evidence of ostium secundum atrial septal defect; and
- Clinical evidence of right ventricular volume overload (i.e., 1.5:1 degree of left to right shunt or right ventricular enlargement).

Independent Health considers percutaneous transcatheter closure of ASDs experimental for migraine prophylaxis and all other indications as the effectiveness has not been established.

Transcatheter closure of secundum atrial septal defects may be medically necessary when using a device that is FDA approved for that purpose and indication.

MediSource, MediSource Connect, Child Health, and Essential Plan:
MediSource, MediSource Connect, Child Health and Essential Plan cover percutaneous transcatheter closure utilizing the Commercial Criteria above.

Background:
A PFO is a is a congenital heart defect in which there is an opening between the atria, allowing oxygen-rich blood to leak into the oxygen-poor blood chambers in the heart. The presence of a PFO has no therapeutic consequence in otherwise healthy adults; however, right-to-left shunting can generate thrombus, with the potential for embolism to the brain or coronary arteries causing stroke or transient ischemic attack (TIA). Most patients with a PFO are asymptomatic. Transcatheter PFO occlusion devices are permanently implanted devices designed to block right-to-left shunt across the atria. Transcatheter occlusion is performed in a cardiac catheterization laboratory, and the patient is typically discharged within 24 hours of the procedure.

Patent foramen ovale may be detected in up to 25% of adults. PFOs may be associated with paradoxical embolus, in which an embolus arising in the venous circulation gains access to the arterial circulation through the PFO, resulting in a stroke or transient ischemic attack (TIA).

Two transcatheter devices received approval for marketing from the U.S. Food and Drug Administration (FDA) in 2002 as a treatment for patient with cryptogenic stroke and patent foramen ovale; the CardioSEAL Septal Occlusion system and Amplatzer Patent Foramen Ovale occluder. Both received approval by the FDA through a Humanitarian Device Exemption (HDE), a category of FDA approval that is applicable to devices that are designed to treat a patient population of fewer than 4,000 patients per year. This approval process requires the manufacturer to submit data on the safety and probable clinical benefit. Clinical trials validating the device's effectiveness are not required.

Following this limited FDA approval, the use of PFO devices increased by over 50-fold, well in excess of the 4,000 per year threshold intended under HDE. As a result, in 2006, the FDA withdrew the HDE approval for these devices. The FDA reiterated the importance of randomized controlled trials of PFO closure devices versus medical therapy.

Atrial septal defect (ASD) is the most common congenital lesion in adults after bicuspid aortic valve. Although patients with this defect are often asymptomatic until adulthood, potential complications of an untreated ASD include atrial arrhythmias, paradoxical embolization, cerebral abscess, right ventricular failure, and pulmonary hypertension that can become irreversible and lead to right-to-left shunting. Mortality rates are similar with surgical and percutaneous ASD closure, the rate of procedural success is comparable or slightly better with surgery, and the rate of early complications and length of hospital stay are reduced with the percutaneous approach.

Three devices have been approved by the U.S. Food and Drug Administration (FDA) for ASD closure: the Amplatzer™ Septal Occluder, the GORE HELEX Septal Occluder (discontinued), and the GORE CARDIOFORM Septal Occluder. Of note, the Gore CARDIOFORM Septal Occluder does not have self-centering properties, which limits its use for larger defects, and it is used mostly for patent foramen ovale closure.

An evaluation of the peer-reviewed scientific literature, including but not limited to subscription materials, has provided Independent Health the basis for its medical necessity coverage outlined above.

Pre-Authorization Required? Yes ☐ No☒

Pre-authorization is not required at the present time. Criteria above will be utilized upon retro-review.

Definitions

Patent foramen ovale (PFO) – is a defect in the septum (wall) between the two upper atrial chambers of the heart. The defect is an incomplete closure of the atrial septum resulting in the creation of a flap or a valve like opening in the atrial septal wall.

Atrial septal defect (ASD) - is a congenital heart defect in which there is an opening between the atria. This defect allows oxygen-rich blood to leak into the oxygen-poor blood chambers in the heart.

Cryptogenic stroke - is an ischemic stroke occurring in the absence of potential cardiac, vascular, pulmonary or neurological sources.

Ostium secundum: is an atrial septal defect with an abnormally large opening in the atrial septum at the site of the foramen ovale and the ostium secundum.

References

Related Policies, Processes and Other Documents
N/A

Non-Regulatory references

American Heart Association (AHA) [web site]. Atrial Septal Defect (ASD). Available at: https://www.heart.org/en/health-topics/congenital-heart-defects/about-congenital-heart-defects/atrial-septal-defect-asd Accessed December 8, 2023

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Centers for Disease and Control Prevention (CDC) [web site]. Facts about Atrioventricular Septal Defect (AVSD). Last reviewed February 2, 2023. Available at: https://www.cdc.gov/ncbddd/heartdefects/avsd.html Accessed December 8, 2023

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Messe SR, Brecker SJD. Stroke associated with patent foramen ovale (PFO): Management. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on December 8, 2023.)

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Regulatory References

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Food and Drug Administration (FDA), [web site]. Center for Devices and Radiological Health (CDRH). CardioSEAL® Septal Occlusion System Transcatheter Cardiac Occlusion Device. No. P000049, December 5, 2001. Available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=320011 Accessed December 8, 2023

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New York State Department of Health. eMedNY [web site]. New York State Medicaid Program Physician –Procedure Codes Section 2 – Medicine, Drugs, and Drug Administration April 2023. Available at: https://www.emedny.org/ProviderManuals/Physician/PDFS/Physician_Procedure_Codes_Sect2.pdf Accessed December 8, 2023

This policy contains medical necessity criteria that apply for this service. Please note that payment for covered services is subject to eligibility criteria, contract exclusions and the limitations noted in the member's contract at the time the services are rendered.

Version Control

Signature / Approval on File? Yes ☒ No☐

Revision Date	Owner	Notes
3/1/2025	Health Care Services	Reviewed
2/1/2024	Health Care Services	Reviewed
1/1/2024	Health Care Services	Revised
2/1/2023	Health Care Services	Reviewed
3/1/2022	Health Care Services	Reviewed
4/1/2021	Health Care Services	Reviewed
5/1/2020	Health Care Services	Revised
6/1/2019	Medical Management	Revised
6/1/2018	Medical Management	Reviewed
6/1/2017	Medical Management	Revised
7/1/2016	Medical Management	Revised
5/1/2016	Medical Management	Revised
5/1/2015	Medical Management	Revised
2/1/2014	Medical Management	Revised

8/18/2012	Medical Management	Reviewed
9/20/2011	Medical Management	Reviewed