Percutaneous Patent Foramen Ovale (PFO) Closure (for Indiana Only)

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Instructions for Use

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Related Policy
- Omnibus Codes

Application

This Medical Policy only applies to the state of Indiana.

Coverage Rationale

Note: This policy does not apply to individuals <18 years of age.

Percutaneous patent foramen ovale closure for the prevention of recurrent ischemic stroke is proven and medically necessary when used according to U.S. Food and Drug Administration (FDA) labeled indications, contraindications, warnings and precautions and all of the following criteria are met:
- History of cryptogenic stroke confirmed by imaging; and
- A cardiologist and a neurologist agree that the stroke is likely embolic in nature; and
- Other causes of ischemic stroke have been ruled out including, but not limited to, carotid disease, hypercoagulable states or atrial fibrillation; and
- Individual is 18-60 years of age

Due to insufficient evidence of efficacy, percutaneous patent foramen ovale closure is unproven and not medically necessary for all other stroke or related neurological indications including, but not limited to, primary prevention of stroke, transient ischemic attacks, and migraine prevention.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

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

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Transcatheter PFO closure is a procedure and, therefore, is not subject to FDA regulation. However, the devices designed for PFO occlusion are subject to FDA regulation. These devices are regulated by the premarket approval process and are classified as transcatheter septal occluders (product code MLV).

The Amplatzer™ PFO Occluder (SJM/Abbott) received FDA premarket approval (P120021) on October 28, 2016. The device is indicated for percutaneous transcatheter closure of a patent foramen ovale (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. Additional information is available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P120021. (Accessed January 3, 2020)

The Gore® Cardioform Septal Occluder (W.L. Gore) received FDA premarket approval (P050006/S060) on July 31, 2017. The device is indicated for the percutaneous, transcatheter closure of the following defects of the atrial septum:

- Ostium secundum atrial septal defects
- 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.

Additional information is available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P050006S060. (Accessed January 3, 2020)

Policy History/Revision Information

Date	Summary of Changes
04/01/2021	• New Medical Policy

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.