New Century Health

Cardio Policy:

Percutaneous Closure of Patent Foramen Ovale (PFO)

POLICY NUMBER UM CARDIO_1417	**SUBJECT** Percutaneous Closure of Patent Foramen Ovale (PFO)	**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 3**
DATES COMMITTEE REVIEWED 11/11/20, 10/14/21, 11/09/21, 10/12/22, 09/13/23	**APPROVAL DATE** September 13, 2023	**EFFECTIVE DATE** September 29, 2023	**COMMITTEE APPROVAL DATES** 11/11/20, 10/14/21, 11/09/21, 10/12/22, 09/13/23
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee	
NCQA STANDARDS UM 2		**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**	**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid	

I. PURPOSE

Indications for determining medical necessity for percutaneous closure of patent foramen ovale (PFO) for the secondary prevention of neurologic events.

II. DEFINITIONS

PFO is a congenital heart defect that allows for unnatural communication between the left and right sides of the heart at the level of the atria. One possible complication of this is that blood clots forming in the venous system have the opportunity to travel from the right side of the heart into the systemic circulation resulting in a paradoxical embolism that can cause neurologic events such as transient ischemic attack (TIA) and ischemic cerebrovascular accident (CVA or stroke) should it enter the cerebral circulation. When a TIA or CVA occurs in a young individual without large-vessel atherosclerosis, small-artery disease, or embolism despite extensive vascular, serological, and cardiac evaluation, the event is termed a cryptogenic stroke and suspicion arises for a paradoxical embolism to be the cause. This initiates a search for a PFO by using transesophageal echocardiography (TEE). Once identified, the treatment has involved secondary prophylaxis against another event by initiating therapy with aspirin, dual anti-platelet therapy, or full anticoagulation, usually with warfarin. More recently, evidence has demonstrated that catheter-based closure of the defect is more effective for preventing recurrent neurologic event than pharmacological treatment

alone for highly selected patients (age ≤60 years) who have an embolic-appearing cryptogenic ischemic stroke and an interatrial connection. Approximately 40% of ischemic strokes without an identifiable cause have a PFO.

Appropriate Use Criteria (AUC score) for a service is one in which the expected incremental information, combined with clinical judgment, exceeds the expected negative consequences by a sufficiently wide margin for a specific indication that the procedure is generally considered acceptable care and a reasonable approach for the indication. The ultimate objective of AUC is to improve patient care and health outcomes in a cost– effective manner but is not intended to ignore ambiguity and nuance intrinsic to clinical decision making.

Appropriate Care- Median Score 7-9

May be Appropriate Care- Median Score 4-6

Rarely Appropriate Care- Median Score 1-3

III. POLICY

Indications for approving a request for medical necessity are:

A. Percutaneous PFO closure is appropriate for patients who have experience a cryptogenic embolic-appearing stroke or TIA who are ≤ 60 years of age and have TEE evidence of interatrial communication that is amenable to percutaneous closure. **(AUC Score 7)**[1, 2, 3, 4]

Limitations

The following are exclusion criteria for percutaneous PFO closure

A. The existence of other stroke risk factors that would not be affected by device closure, such as but not limited to a cardiac source of embolism apart from PFO, rheumatic mitral stenosis, significant atherosclerosis of the carotid and intracranial circulation, protruding or mobile aortic plaque, coagulopathy, atrial fibrillation or flutter, or vasculitis involving the carotid circulation

B. Presence of an inferior vena cava filter

C. Elevated bleeding risk or coagulopathy that would prevent the use of dual anti-platelet therapy for six months, and aspirin indefinitely thereafter

D. Requests for services that are part of a surveillance protocol for patients who are involved in a clinical trial are considered out of scope (OOS) for New Century Health and cannot be reviewed.

IV. PROCEDURE

A. To review a request for medical necessity, the following items must be submitted for review
   1. Medical notes from a Cardiologist and a Neurologist that indicate the need for the procedure and document that no other obvious etiology for the neurologic event has been discovered
   2. A TEE report that documents the presence of the defect and addresses the suitability of the anatomy for device placement
   3. Results of diagnostic testing performed to rule out other causes of neurologic event i.e. vascular disease, hypercoagulable state, occult atrial fibrillation, consisting at least of a carotid duplex or CTA/MRA report, evidence of hematological workup, and evidence of heart rhythm monitoring

B. Primary code appropriate for this service: 93580

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

1. Shah, R et al. Device Closure Versus Medical Therapy Alone for Patent Foramen Ovale in Patients with Cryptogenic Stroke: A Systematic Review and Meta-analysis. Ann Intern Med. 2018;168(5):335. Epub 2018 Jan 9.
2. Fareed Moses S. Collado et al. Patent Foramen Ovale Closure for Stroke Prevention and Other Disorders. Journal of the American Heart Association. 2018;7(12) https://doi.org/10.1161/JAHA.117.007146
3. Saver, JL et al. Long-Term Outcomes of Patent Foramen Ovale Closure or Medical Therapy after Stroke. N Engl J Med. 2017;377(11):1022.
4. Mas JL et al. Patent Foramen Ovale Closure or Anticoagulation vs. Antiplatelets after Stroke. N Engl J Med. 2017;377(11):1011.
5. NCQA UM 2023 Standards and Elements.

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