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Approval and implementation dates for specific health plans may vary. Please consult the applicable health plan for more details.

Clinical Appropriateness Guidelines

Cardiovascular

Appropriate Use Criteria: Catheter-Based Closure of Patent Foramen Ovale

Proprietary

Table of Contents

Description and Application of the Guidelines

The Carelon Clinical Appropriateness Guidelines (hereinafter “the Carelon Clinical Appropriateness Guidelines” or the “Guidelines”) are designed to assist providers in making the most appropriate treatment decision for a specific clinical condition for an individual. The Guidelines establish objective and evidence-based criteria for medical necessity determinations, where possible, that can be used in support of the following:

- To establish criteria for when services are medically necessary
- To assist the practitioner as an educational tool
- To encourage standardization of medical practice patterns
- To curtail the performance of inappropriate and/or duplicate services
- To address patient safety concerns
- To enhance the quality of health care
- To promote the most efficient and cost-effective use of services

The Carelon guideline development process complies with applicable accreditation and legal standards, including the requirement that the Guidelines be developed with involvement from appropriate providers with current clinical expertise relevant to the Guidelines under review and be based on the most up-to-date clinical principles and best practices. Resources reviewed include widely used treatment guidelines, randomized controlled trials or prospective cohort studies, and large systematic reviews or meta-analyses. Carelon reviews all of its Guidelines at least annually.

Carelon makes its Guidelines publicly available on its website. Copies of the Guidelines are also available upon oral or written request. Additional details, such as summaries of evidence, a list of the sources of evidence, and an explanation of the rationale that supports the adoption of the Guidelines, are included in each guideline document.

Although the Guidelines are publicly available, Carelon considers the Guidelines to be important, proprietary information of Carelon, which cannot be sold, assigned, leased, licensed, reproduced or distributed without the written consent of Carelon. Use of the Guidelines by any external AI entity without the express written permission of Carelon is prohibited.

Carelon applies objective and evidence-based criteria, and takes individual circumstances and the local delivery system into account when determining the medical appropriateness of health care services. The Carelon Guidelines are just guidelines for the provision of specialty health services. These criteria are designed to guide both providers and reviewers to the most appropriate services based on a patient’s unique circumstances. In all cases, clinical judgment consistent with the standards of good medical practice should be used when applying the Guidelines. Guideline determinations are made based on the information provided at the time of the request. It is expected that medical necessity decisions may change as new information is provided or based on unique aspects of the patient’s condition. The treating clinician has final authority and responsibility for treatment decisions regarding the care of the patient and for justifying and demonstrating the existence of medical necessity for the requested service. The Guidelines are not a substitute for the experience and judgment of a physician or other health care professionals. Any clinician seeking to apply or consult the Guidelines is expected to use independent medical judgment in the context of individual clinical circumstances to determine any patient’s care or treatment.

The Guidelines do not address coverage, benefit or other plan specific issues. Applicable federal and state coverage mandates take precedence over these clinical guidelines, and in the case of reviews for Medicare Advantage Plans, the Guidelines are only applied where there are not fully established CMS criteria. If requested by a health plan, Carelon will review requests based on health plan medical policy/guidelines in lieu of the Carelon Guidelines. Pharmaceuticals, radiotracers, or medical devices used in any of the diagnostic or therapeutic interventions listed in the Guidelines must be FDA-approved or conditionally approved for the intended use. However, use of an FDA-approved or conditionally approved product does not constitute medical necessity or guarantee reimbursement by the respective health plan.

The Guidelines may also be used by the health plan or by Carelon for purposes of provider education, or to review the medical necessity of services by any provider who has been notified of the need for medical necessity

review, due to billing practices or claims that are not consistent with other providers in terms of frequency or some other manner.

General Clinical Guideline

Clinical Appropriateness Framework

Critical to any finding of clinical appropriateness under the guidelines for a specific diagnostic or therapeutic intervention are the following elements:

- Prior to any intervention, it is essential that the clinician confirm the diagnosis or establish its pretest likelihood based on a complete evaluation of the patient. This includes a history and physical examination and, where applicable, a review of relevant laboratory studies, diagnostic testing, and response to prior therapeutic intervention.
- The anticipated benefit of the recommended intervention is likely to outweigh any potential harms, including from delay or decreased access to services that may result (net benefit).
- Widely used treatment guidelines and/or current clinical literature and/or standards of medical practice should support that the recommended intervention offers the greatest net benefit among competing alternatives.
- There exists a reasonable likelihood that the intervention will change management and/or lead to an improved outcome for the patient.

Providers may be required to submit clinical documentation in support of a request for services. Such documentation must a) accurately reflect the clinical situation at the time of the requested service, and b) sufficiently document the ordering provider's clinical intent.

If these elements are not established with respect to a given request, the determination of appropriateness will most likely require a peer-to-peer conversation to understand the individual and unique facts that would justify a finding of clinical appropriateness. During the peer-to-peer conversation, factors such as patient acuity and setting of service may also be taken into account to the extent permitted by law.

Simultaneous Ordering of Multiple Diagnostic or Therapeutic Interventions

Requests for multiple diagnostic or therapeutic interventions at the same time will often require a peer-to-peer conversation to understand the individual circumstances that support the medical necessity of performing all interventions simultaneously. This is based on the fact that appropriateness of additional intervention is often dependent on the outcome of the initial intervention.

Additionally, either of the following may apply:

- Current literature and/or standards of medical practice support that one of the requested diagnostic or therapeutic interventions is more appropriate in the clinical situation presented; or
- One of the diagnostic or therapeutic interventions requested is more likely to improve patient outcomes based on current literature and/or standards of medical practice.

Repeat Diagnostic Intervention

In general, repeated testing of the same anatomic location for the same indication should be limited to evaluation following an intervention, or when there is a change in clinical status such that additional testing is required to determine next steps in management. At times, it may be necessary to repeat a test using different techniques or protocols to clarify a finding or result of the original study.

Repeated testing for the same indication using the same or similar technology may be subject to additional review or require peer-to-peer conversation in the following scenarios:

- Repeated diagnostic testing at the same facility due to technical issues
- Repeated diagnostic testing requested at a different facility due to provider preference or quality concerns

- Repeated diagnostic testing of the same anatomic area based on persistent symptoms with no clinical change, treatment, or intervention since the previous study
- Repeated diagnostic testing of the same anatomic area by different providers for the same member over a short period of time

Repeat Therapeutic Intervention

In general, repeated therapeutic intervention in the same anatomic area is considered appropriate when the prior intervention proved effective or beneficial and the expected duration of relief has lapsed. A repeat intervention requested prior to the expected duration of relief is not appropriate unless it can be confirmed that the prior intervention was never administered. Requests for ongoing services may depend on completion of previously authorized services in situations where a patient's response to authorized services is relevant to a determination of clinical appropriateness.

Catheter-Based Closure of Patent Foramen Ovale

General Information

Guideline Scope

This guideline addresses the appropriateness of transcatheter closure of patent foramen ovale (PFO). Transcatheter delivery of devices to address other congenital atrial septal abnormalities is not addressed. Surgical closure of PFO is not addressed. Closure of PFO for indications other than those listed in this guideline, including but not limited to treatment of migraine, is considered not medically necessary.

Background

Patent foramen ovale is found in up to 25% of the general population. When PFO is found in a patient who has had a stroke, the association may be incidental or causal. If incidental, then closure of the PFO would not be expected to change outcomes. Conversely, if the PFO is part of the mechanism of stroke (e.g., paradoxical embolization from the venous circulation or local thrombus formation on the atrial septum with subsequent embolization), and if the stroke is likely to recur, then closure of the defect would be expected to reduce the risk of subsequent stroke. It is imperative that other possible causes of stroke be excluded before a decision is made to close the PFO. Since other causes of stroke (atrial fibrillation, intracranial and extracranial vascular disease, valvular disease, etc.) are more prevalent as patients age, PFO related stroke becomes less likely. The ROPE score addresses the likelihood that an embolic stroke is PFO related. In addition to age, it considers other stroke risk factors (hypertension, tobacco use, and diabetes), the findings on brain imaging, and history of prior stroke. In addition to these clinical features, the causal relationship between stroke and PFO is related to the imaging characteristics of the PFO and the atrial septum. A thrombus straddling the PFO is associated with very high risk of causal association. A large-shunt PFO or an atrial septal aneurysm (ASA) confers high risk with concomitant pulmonary embolus (PE) or deep vein thrombus (DVT) and medium risk without. In patients with small-shunt PFOs without ASA, the risk of causal association is low.

Patients who have an indication for long-term anticoagulation are unlikely to benefit from PFO closure since their risk of venous or intracardiac thrombosis is addressed by anticoagulation thereby lowering their risk of subsequent PFO related stroke. In those with an indication for short-term anticoagulation (e.g., those with concomitant PE or DVT at the time of stroke) closure of the PFO (if otherwise appropriate) can be deferred until the course of anticoagulation is complete.

Definitions

RoPE (Risk of Paradoxical Embolism) score: A scoring tool which helps predict which PFO patients with embolic stroke are likely to have had the stroke as a consequence of the PFO. Higher scores suggest a causal relationship between stroke and PFO. The tool (https://www.mdcalc.com/calc/3902/risk-paradoxical-embolism-rope-score) assigns a score based on age, presence or absence of alternative causes of stroke (hypertension, diabetes, smoking history), history of prior stroke or TIA, and cortical infarct on brain imaging.

High-risk echocardiogram: Any of the following findings represents a high-risk echo:

- PFO with straddling thrombus
- PFO with atrial septal aneurysm
- Large-shunt PFO defined as a single frame showing > 20 microbubbles in the left atrium within 3 cardiac cycles following opacification of the right atrium with agitated saline contrast (with or without Valsalva maneuver)

Comprehensive evaluation of embolic stroke: A stroke can be considered to be cryptogenic (and therefore more likely related to a PFO) when no other explanation for the stroke is evident after the following investigations:

- Brain imaging

- Neurovascular imaging
- Exclusion of atrial fibrillation. This requires no less than 30 days of rhythm monitoring showing no atrial fibrillation episode lasting longer than 1 hour.
- Cardiovascular imaging to exclude other sources of embolus
- Exclusion of hypercoagulable state

Abbreviations

PFO Patent foramen ovale

ASA Atrial septal aneurysm

DVT Deep venous thrombosis

PE Pulmonary embolus

RoPE Risk of paradoxical embolism

Clinical Indications

Percutaneous transcatheter closure of PFO is considered medically necessary for individuals who meet ALL of the following criteria:

- Aged 60 years or younger
- Embolic stroke of unknown cause despite comprehensive evaluation (as described above)
- High RoPE score (> 6) or high-risk echocardiogram with low RoPE score (< or = 6)
- No concurrent indication for anticoagulation (e.g., atrial fibrillation, mechanical heart valve prosthesis, pulmonary embolus, deep vein thrombus, etc.)
- Not scheduled for cardiac surgery

References

1. Ahmad Y, Howard JP, Arnold A, et al. Patent foramen ovale closure vs. medical therapy for cryptogenic stroke: a meta-analysis of randomized controlled trials. Eur Heart J. 2018;39(18):1638-49.
2. Ando T, Holmes AA, Pahuja M, et al. Meta-Analysis Comparing Patent Foramen Ovale Closure Versus Medical Therapy to Prevent Recurrent Cryptogenic Stroke. Am. J. Card. 2018;121(5):649-55.
3. Chen X, Chen SD, Dong Y, et al. Patent foramen ovale closure for patients with cryptogenic stroke: A systematic review and comprehensive meta-analysis of 5 randomized controlled trials and 14 observational studies. CNS Neurosci Ther. 2018;24(10):853-62.
4. Dia A, Cifu AS, Shah AP. Management of Patients With a Patent Foramen Ovale With History of Stroke or TIA. JAMA. 2021;325(1):81-2.
5. Garg A, Thawabi M, Rout A, et al. Recurrent Stroke Reduction with Patent Foramen Ovale Closure versus Medical Therapy Based on Patent Foramen Ovale Characteristics: A Meta-Analysis of Randomized Controlled Trials. Cardiology. 2019;144(1-2):40-9.
6. Gladstone DJ, Lindsay MP, Douketis J, et al. Canadian Stroke Best Practice Recommendations: Secondary Prevention of Stroke Update 2020. Can J Neurol Sci. 2022;49(3):315-37.
7. Kavinsky CJ, Szerlip M, Goldsweig AM, et al. SCAI Guidelines for the Management of Patent Foramen Ovale. JSCAI. 2022;1(4):100039.
8. Kent DM, Saver JL, Kasner SE, et al. Heterogeneity of Treatment Effects in an Analysis of Pooled Individual Patient Data From Randomized Trials of Device Closure of Patent Foramen Ovale After Stroke. JAMA. 2021;326(22):2277-86.
9. Kent DM, Saver JL, Ruthazer R, et al. Risk of Paradoxical Embolism (RoPE)-Estimated Attributable Fraction Correlates With the Benefit of Patent Foramen Ovale Closure: An Analysis of 3 Trials. Stroke. 2020;51(10):3119-23.
10. Kleindorfer DO, Towfighi A, Chaturvedi S, et al. 2021 Guideline for the Prevention of Stroke in Patients With Stroke and Transient Ischemic Attack: A Guideline From the American Heart Association/American Stroke Association. Stroke. 2021;52(7):e364-e467.

11. Kolokathis K, Thomopoulos C, Tsioufis K. Net clinical benefit of PFO closure versus medical treatment in patients with cryptogenic stroke: A systematic review and meta-analysis. Hellenic J Cardiol. 2023;70:46-52.
12. Lee PH, Song JK, Kim JS, et al. Cryptogenic Stroke and High-Risk Patent Foramen Ovale: The DEFENSE-PFO Trial. J Am Coll Cardiol. 2018;71(20):2335-42.
13. Liu Y, Wu Y, Xiong L. Surgical vs. drug therapy in patients with patent foramen ovale and cryptogenic stroke. Herz. 2021;46(3):250-4.
14. Mas JL, Derumeaux G, Guillon B, et al. Patent Foramen Ovale Closure or Anticoagulation vs. Antiplatelets after Stroke. N Engl J Med. 2017;377(11):1011-21.
15. Mas JL, Guillon B, Charles-Nelson A, et al. Patent foramen ovale closure in stroke patients with migraine in the CLOSE trial. The CLOSE-MIG study. Eur J Neurol. 2021;28(8):2700-7.
16. Mattle HP, Evers S, Hildick-Smith D, et al. Percutaneous closure of patent foramen ovale in migraine with aura, a randomized controlled trial. Eur Heart J. 2016;37(26):2029-36.
17. Messé SR, Gronseth GS, Kent DM, et al. Practice advisory update summary: Patent foramen ovale and secondary stroke prevention: Report of the Guideline Subcommittee of the American Academy of Neurology. Neurology. 2020;94(20):876-85.
18. Morais LA, Sousa L, Fiarresga A, et al. RoPE Score as a Predictor of Recurrent Ischemic Events After Percutaneous Patent Foramen Ovale Closure. Int Heart J. 2018;59(6):1327-32.
19. Nasir UB, Qureshi WT, Jogu H, et al. Updated meta-analysis of closure of patent foramen ovale versus medical therapy after cryptogenic stroke. Cardiovasc Revasc Med. 2019;20(3):187-93.
20. NHS England Specialised Services Clinical Reference Group for Cardiac Services. Percutaneous patent foraman ovale closure for the prevention of recurrent cerebral embolic stroke in adults (around age 60 years and under). Redditch (UK): NHS England; 2019. p. 23.
21. Pristipino C, Sievert H, D'Ascenzo F, et al. European position paper on the management of patients with patent foramen ovale. General approach and left circulation thromboembolism. Eur Heart J. 2019;40(38):3182-95.
22. Saver JL, Carroll JD, Thaler DE, et al. Long-Term Outcomes of Patent Foramen Ovale Closure or Medical Therapy after Stroke. N Engl J Med. 2017;377(11):1022-32.
23. Sondergaard L, Kasner SE, Rhodes JF, et al. Patent Foramen Ovale Closure or Antiplatelet Therapy for Cryptogenic Stroke. N Engl J Med. 2017;377(11):1033-42.
24. Strambo D, Sirimarco G, Nannoni S, et al. Embolic Stroke of Undetermined Source and Patent Foramen Ovale: Risk of Paradoxical Embolism Score Validation and Atrial Fibrillation Prediction. Stroke. 2021;52(5):1643-52.
25. Tobis JM, Charles A, Silberstein SD, et al. Percutaneous Closure of Patent Foramen Ovale in Patients With Migraine: The PREMIUM Trial. J Am Coll Cardiol. 2017;70(22):2766-74.
26. Turc G, Calvet D, Guerin P, et al. Closure, Anticoagulation, or Antiplatelet Therapy for Cryptogenic Stroke With Patent Foramen Ovale: Systematic Review of Randomized Trials, Sequential Meta-Analysis, and New Insights From the CLOSE Study. J Am Heart Assoc. 2018;7(12):17.

Codes

The following code list is not meant to be all-inclusive. Authorization requirements will vary by health plan. Please consult the applicable health plan for guidance on specific procedure codes.

Specific CPT codes for services should be used when available. Nonspecific or not otherwise classified codes may be subject to additional documentation requirements and review.

CPT/HCPCS

93580	Percutaneous transcatheter closure of congenital interatrial communication [*when specified as closure of patent foramen ovale*]

History

Status	Review Date	Effective Date	Action
Reaffirmed	01/29/2026	Unchanged	Independent Multispecialty Physician Panel review. Clarification added to Guideline Scope. Guideline reaffirmed.
Reaffirmed	07/17/2025	Unchanged	IMPP review. Guideline reaffirmed.
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