July 9, 2020

David W. Brewster
Director, External Affairs
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Re: SURG.00032 Patent Foramen Ovale and Left Atrial Appendage Closure Devices for Stroke Prevention

The Society for Cardiovascular Angiography and Interventions (SCAI) is a non-profit professional association with over 4,500 members representing interventional cardiologists. SCAI promotes excellence in interventional cardiovascular medicine through education, representation and the advancement of quality standards to enhance patient care.

Patent Foramen Ovale

Anthem’s policy covers:

“Transcatheter closure of a patent foramen ovale (PFO) using a U.S. Food and Drug Administration (FDA) approved device approved for that indication is considered medically necessary for:

A. 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

B. in individuals 60 years old and younger with a history of cryptogenic stroke and either a) have an atrial septal aneurysm or b) have large interatrial shunt (see definition section).

Transcatheter closure of a patent foramen ovale for the prevention of stroke is considered investigational and not medically necessary when the criteria above are not met.”
In 2017 and 2018, four pivotal randomized multicenter studies (RESPECT\textsuperscript{1}, REDUCE\textsuperscript{2}, CLOSE\textsuperscript{3}, and DEFENSE-PFO\textsuperscript{4}) definitively demonstrated PFO closure to be superior to antiplatelet therapy for the prevention of a first recurrence of paradoxical embolic stroke, leading the US Food and Drug Administration (FDA) to approve the Amplatzer PFO Occluder as well as the Cardioform device (WL Gore, Newark, DE) for percutaneous PFO closure.

These four trials did not specify that patients had to have a subsequent stroke while on medical therapy. Anthem’s requirement that a patient who has already had a stroke then take medical therapy, proven four times to be inferior to PFO closure, is antiquated and not evidence-based; the requirement that patients have a second stroke before receiving PFO closure is simply cruel. Indeed, the American Academy of Neurology recommended in 2020 that:

1. In patients younger than 60 years with a PFO and an embolic-appearing infarct and no other mechanism of stroke identified, clinicians may recommend closure following a discussion of potential benefits (reduction of stroke recurrence) and risks (procedural complication and atrial fibrillation) (Level C)\textsuperscript{5}.
2. PFO closure may be offered in other populations, such as for a patient who is 60−65 years old with a very limited degree of traditional vascular risk factors (i.e., hypertension, diabetes, hyperlipidemia, or smoking) and no other mechanism of stroke detected following a thorough evaluation, including prolonged monitoring for atrial fibrillation (Level B)\textsuperscript{5}.

Indeed, the DEFENSE-PFO\textsuperscript{4} trial enrolled patients over age 60 and demonstrated benefit with respect to prevention of recurrent stroke in patients with high-risk PFO anatomy.

An eight-society European consensus statement has recommended since 2018 “to perform percutaneous closure of a PFO in carefully selected patients”\textsuperscript{6}. A 2019 US consensus statement on operator and institutional requirements has been published\textsuperscript{7}, and US cardiology guidelines supporting the appropriate utilization of PFO closure are currently being drafted.

**Left Atrial Appendage Occlusions**

Anthem denies any coverage of Left Atrial Appendage Occlusions stating that: “Currently there is insufficient clinical evidence on the safety and efficacy to support the use of exclusion of the LAA with a cardiac device for the management of atrial fibrillation.”
To date, there have been more than 110,000 LAAO devices implanted. Two major randomized trials have demonstrated safety and efficacy\textsuperscript{8,9}. The National Cardiovascular Data Registry (NCDR) has enrolled >38,000 patients and demonstrated very low adverse event rates (2.16\%)\textsuperscript{10}. The 1025-patient EWOLUTION registry reported a 1-year ischemic stroke rate of 1.1\%, representing an 84\% reduction in risk vs. the stroke rate predicted by the CHA\textsubscript{2}-DS\textsubscript{2}-VASc model\textsuperscript{11}. The Watchman device was approved by the US Food and Drug Administration (FDA) in 2015 and has been reimbursed by the Center for Medicare and Medicaid Services (CMS) since 2016. In light of clinical trial data, the 2019 multisociety guidelines (American Heart Association, American College of Cardiology, and Heart Rhythm Society) and 2016 European guidelines recommend consideration of LAAO in patients at increased risk of stroke who have contraindications to long-term anticoagulation, similar to the procedure’s CMS approval\textsuperscript{12,13}. The U.S. recommendation was given a class IIb only because of slight discordance between the FDA and CMS approval language, and the European recommendation was given a class IIb because data were far more limited at the time of publication in 2016 than they are at present.

New data have also been recently published. The PRAGUE-17 study bolsters the argument for considering LAA closure as an alternative to DOACs, the current standard of care in atrial fibrillation in high bleeding risk patients\textsuperscript{15}. PRAGUE-17 concluded that, among patients at high risk for stroke and increased risk of bleeding, LAAC was noninferior to DOACs in preventing major AF-related cardiovascular, neurological, and bleeding events.

The evidence is clear that LAAO is an appropriate procedure as an alternative to anticoagulation to reduce stroke risk in patients with atrial fibrillation. Furthermore, LAAO is actually expected to be more cost effective than anticoagulation over 5 years\textsuperscript{14}. 
We thank Drs. Lyndon Box (Chair of Government Relations Committee), Joaquin Cigarroa (Co-Chair of the Government Relations Committee), Nirmanmoh Bhatia, and Andrew M. Goldsweig, for their efforts in developing this response. If we can be of any assistance as Anthem reconsiders this policy, please do not hesitate to contact Wayne Powell at 703.772.7910 or wpowell@scai.org.

Sincerely

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President

Lyndon Box, MD, FSCAI  
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References


