Transcatheter Closure of Patent Foramen Ovale for Stroke Prevention

I. Description

The foramen ovale, a component of fetal cardiovascular circulation, consists of a communication between the right and left atrium that functions as a vascular bypass of the uninflated lungs. The ductus arteriosus is another feature of the fetal cardiovascular circulation, consisting of a connection between the pulmonary artery and the distal aorta. Prior to birth, the foramen ovale is held open by the large flow of blood into the left atrium from the inferior vena cava. Over a course of months after birth, an increase in left atrial pressure and a decrease in right atrial pressure result in the permanent closure of the foramen ovale in most individuals. However, patent foramen ovale (PFO) is a common finding in normal adults, detected in up to 25% of adults. In some epidemiologic studies, PFO has been associated with cryptogenic stroke, a type of stroke defined as an ischemic stroke occurring in the absence of potential cardiac, pulmonary, vascular, or neurological sources.

The role of PFO in patients with cryptogenic stroke remains controversial, although an association seems likely in younger patients with atrial septal aneurysms and PFO. The mechanism of cryptogenic stroke in these patients is presumed to be paradoxical embolism via right-to-left shunt across the PFO. Treatment options include medical therapy with antiplatelet or anticoagulant therapy based in part on the theory that clotting disorders may be present in individuals with embolic stroke. Alternative treatments include open surgery or transcatheter approaches using a PFO closure device in individuals with recurrent cryptogenic stroke due to presumed paradoxical embolism who have failed conventional drug therapy with anticoagulants.

Transcatheter closure of secundum atrial septal defects may be considered medically necessary when using a device that has been FDA approved for that purpose and used according to the labeled indications.

At present, 2 devices are FDA-approved for ASD closure: the Amplatzer™ Septal Occluder (St. Jude Medical, Minneapolis, MN), and the GORE HELEX™ Septal Occluder (W.L. Gore &
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Associates Inc., Newark, DE). The Amplatzer Septal Occluder was approved through FDA’s premarket approval process in June 2002. The Amplatzer device is intended for the occlusion of ASDs in the secundum position or in patients who have undergone a fenestrated Fontan procedure who require closure of the fenestration. Patients indicated for ASD closure have echocardiographic evidence of ostium secundum ASD and clinical evidence of right ventricular volume overload.

The Gore Helix Septal Occluder was approved through the premarket approval process in August 2006. It is indicated for the percutaneous, transcatheter closure of ostium secundum ASDs.

On October 17, 2013 the FDA issued a warning alerting health care providers and patients that in very rare instances, tissue surrounding the Amplatzer Atrial Septal Occluder (ASO) can break down (erode) and result in life-threatening emergencies that require immediate surgery. According to published estimates, these events occur in approximately 1 to 3 of every 1,000 patients implanted with the Amplatzer ASO. As of March 31, 2013, there have been 234,103 Amplatzer ASO devices sold worldwide. Physicians and patients should follow the FDA recommendations listed on the warning.

II. Criteria/Guidelines

Transcatheter closure of PFO is covered (subject to Limitations and Administrative Guidelines) for the prevention of subsequent stroke in patients with a documented history of cryptogenic stroke and one of the following:

A. The patient has failed conventional drug therapy (e.g., warfarin, anti-platelet therapy);
B. The patient is not a candidate for conventional drug therapy (e.g., intolerance, allergy, extremely young age); or
C. The patient is 60 years old or younger and has a complicating high risk factor such as co-existing thrombophilia, deep venous thrombosis or pulmonary embolism documented at the time of stroke, stroke occurring during Valsalva maneuver, or atrial septal aneurysm with large shunt.

III. Limitations

A. Transcatheter closure of PFO has not been shown to improve health outcomes for any other condition not listed above.
B. Procedures performed with non-FDA-approved devices are not covered.

IV. Administrative Guidelines

A. Precertification is required. To precertify, complete HMSA’s Precertification Request and mail or fax the form, or use iExchange as indicated. Include the following documentation:
1. Patient’s history and physical examination;
2. Clinical notes documenting previous stroke; and
3. Previous treatments that were tried and failed, or documentation describing the patient’s intolerance to conventional therapy.
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B. Applicable Codes:

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<thead>
<tr>
<th>CPT</th>
<th>Description</th>
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<tbody>
<tr>
<td>93580</td>
<td>Percutaneous transcatheter closure of congenital interatrial communication (ie, fontan fenstration, atrial septal defect) with implant [when specified as for patent foramen ovale]</td>
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<tr>
<th>ICD-10 Procedure</th>
<th>Description</th>
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<td>02US3JZ</td>
<td>Supplement atrial septum with synthetic substitute, percutaneous approach</td>
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<tr>
<td>02US4JZ</td>
<td>Supplement atrial septum with synthetic substitute, percutaneous endoscopic approach</td>
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V. Important Reminder

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

VI. References


