Transcatheter Closure of Patent Foramen Ovale for Stroke Prevention

Policy Number: MM.06.021
Original Effective Date 08/01/2013
Line of Business: HMO; PPO; QUEST Integration
Current Effective Date: 02/27/2015
Section: Surgery
Place(s) of Service: Outpatient; Inpatient

I. Description

Patent Foramen Ovale (PFO) 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, 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, through the PFO and who have failed conventional drug therapy with anticoagulants.

On October 17, 2013 the FDA issued a warning alerting health care providers and patients that in very rare instances, tissue surrounding the Amplatzer 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)
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. Complete HMSA’s Precertification request and mail or fax the form as indicated. Include the following documentation:
   1. Patient’s history and physical
   2. Clinical notes documenting previous stroke
   3. Previous treatments that were tried and failed, or documentation describing the patient’s intolerance to conventional therapy

B. Applicable Code:

<table>
<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>
</tr>
</tbody>
</table>

ICD-9 Procedure  Description
35.52 Repair of atrial septal defect with prosthesis, closed technique [when specified as for patent foramen ovale]

C. ICD-10 procedure codes are provided for your information. These will not become effective until 10/1/2014:

<table>
<thead>
<tr>
<th>ICD-10 Procedure</th>
<th>Description</th>
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<tr>
<td>02U53JZ</td>
<td>Supplement atrial septum with synthetic substitute, percutaneous approach</td>
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</table>
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5. 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

3. UpToDate. Treatment of atrial septal abnormalities (PFO, ASD, and ASA) for prevention of stroke in adults. Literature review current through February 2012.

9. FDA safety communication. Rare Serious Erosion Events Associated with St. Jude Amplatzer Atrial Septal Occluder (ASO). Date Issued October 17, 2013.