Medical Policy
Closure Devices for Patent Foramen Ovale and Atrial Septal Defects

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- Policy: Medicare
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Policy Number: 121
BCBSA Reference Number: 2.02.09

Related Policies
- Transcatheter Closure of Patent Ductus Arteriosus, #336

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity
Medicare HMO Blue℠ and Medicare PPO Blue℠ Members

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

Closure of a patent foramen ovale using a transcatheter approach is INVESTIGATIONAL.

Prior Authorization Information
Commercial Members: Managed Care (HMO and POS)
Prior authorization is NOT required.

Commercial Members: PPO, and Indemnity
Prior authorization is NOT required.

Medicare Members: HMO Blue℠
Prior authorization is NOT required.

Medicare Members: PPO Blue℠
Prior authorization is NOT required.

CPT Codes / HCPCS Codes / ICD-9 Codes
The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member. A draft of future ICD-10 Coding related to this document, as it might look today, is included below for your reference.
Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

### CPT Codes

<table>
<thead>
<tr>
<th>CPT codes</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>93580</td>
<td>Percutaneous transcatheter closure of congenital interatrial communication (ie, Fontan fenestration, atrial septal defect) with implant</td>
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### ICD-9 Diagnosis Codes

<table>
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<tr>
<th>ICD-9-CM codes:</th>
<th>Code Description</th>
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<tr>
<td>745.5</td>
<td>Ostium secundum type atrial septal defect</td>
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</table>

### ICD-10 Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10-CM Diagnosis codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>Q21.1</td>
<td>Atrial septal defect</td>
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### Description

**Atrial Septal Defect**

Atrial septal defects (ASD) represent an abnormality in the development of the heart that results in free communication between the atria. ASDs are categorized into ostium secundum ASDs and ostium primum ASDs. Ostium secundum describes defects that are located midseptally and are typically near the fossa ovalis. Ostium primum defects lie immediately adjacent to the atrioventricular valves and occur commonly in patients with Down's syndrome.

**Patent Foramen Ovale**

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 un-inflated lungs. 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 patients. However, a patent foramen ovale (PFO) may be detected in up to 25% of adults. Although common, PFOs are typically clinically insignificant but they may be associated with paradoxical embolus, resulting in a stroke or transient ischemic attack.

Examples of closure devices for PFO include the CardioSeal Septal Occlusion System from NNMT Medical and the AMPLATZER™ Patent Foramen Ovale Occluder from AGA Medical. All PFO closure devices are considered investigational regardless of the commercial name, the manufacturer or FDA approval status.

Examples of closure devices for ASD include The AMPLATZER™ Septal Occluder from AGA medical, and the GORE HELEX™ Septal Occluder from Gore Medical. All ASD are considered investigational regardless of the commercial name, the manufacturer or FDA approval status except when used for the medically necessary indications that are consistent with the policy statement.

### Summary

**Atrial Septal Defect**

Nonrandomized comparative studies and single arm case series show high success rates of closure using closure devices approaching the high success rates of surgery. The percutaneous approach has a low complication rate, and avoids the morbidity and complications of open surgery. If the percutaneous approach is unsuccessful, ASD closure can be achieved using surgery. Because of the advantages of percutaneous closure over open surgery, the use of percutaneous ASD closure devices can be considered medically necessary.
Patent Foramen Ovale
The evidence does not permit conclusions as to whether PFO closure improves outcomes for patients with cryptogenic stroke and PFO. The causal link between cryptogenic stroke and PFO is not strong enough that success in closure of the PFO alone can be considered a clinical outcome. Two nonrandomized comparative studies do not show significant differences in recurrence rate of stroke or TIA between PFO closure and medical therapy. While the observational data suggest that recurrence of stroke or TIA may be lower following PFO closure, these data are prone to bias and are not definitive. Ongoing randomized, controlled trials, which have been slow in accruing patients, will provide higher quality evidence on this question when they are completed. Some expert groups recommend that PFO closure should be considered for patients who have failed medical therapy. However, since closure devices do not have FDA approval, other options may be explored, including surgical repair. For these reasons, PFO closure is considered investigational.

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tr>
<td>5/2014</td>
<td>Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.</td>
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<tr>
<td>12/2013</td>
<td>New references from BCBSA National medical policy.</td>
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<tr>
<td>4/2013</td>
<td>New references from BCBSA National medical policy.</td>
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<tr>
<td>7/2010</td>
<td>Review of BCBSA policy. No changes to policy statements.</td>
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Information Pertaining to All Blue Cross Blue Shield Medical Policies
Click on any of the following terms to access the relevant information:
- Medical Policy Terms of Use
- Managed Care Guidelines
- Indemnity/PPO Guidelines
- Clinical Exception Process
- Medical Technology Assessment Guidelines

References


