I. Policy: Transcatheter Closure Devices for Cardiac Defects

II. Purpose/Objective:
To provide a policy of coverage regarding Transcatheter Closure Devices for Cardiac Defects

III. Responsibility:
A. Medical Directors
B. Medical Management

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) The service or benefit will assist the Member to achieve or maintain maximum functional
capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

DESCRIPTION:
Transcatheter closure devices for treatment of cardiac defects or are permanent cardiac implants designed to close defects between chambers of the heart. The device is implanted during a transcatheter hole closure procedure performed in the cardiac catheterization laboratory. By being less invasive, it is believed to present fewer risks than open heart surgery.

INDICATIONS:
Arterial Septal Defects
The use of a transcatheter closure device for the treatment of secundum atrial septal defects (ASDs) is considered medically necessary when using an FDA approved closure device and ALL of the following criteria are met:
1. Echocardiographic evidence of an atrial septal defect less than 20 mm in diameter; AND
2. There is adequate rim tissue (at least 5 mm) surrounding the defect; AND
3. Clinical evidence of right ventricular volume overload (e.g., right ventricular enlargement or 1.5:1 ratio of left to right shunt)

Ventricular Septal Defects
The use of a transcatheter closure device for the treatment of ventricular septal defects (VSDs) is considered medically necessary when using an FDA approved closure device and ALL of the following criteria are met:
1. The defect is of significant size to warrant closure; AND
2. The member is considered a high risk for standard transatrial or transarterial surgical closure due to any of the following:
   a. A left ventriculotomy or an extensive right ventriculotomy is required; or
   b. A failed previous VSD closure; or
   c. Multiple apical and/or anterior muscular VSD (i.e. Swiss Cheese Septum); or
   d. A posterior apical VSD covered by trabeculae

Patent Foramen Ovale
The use of transcatheter closure device for the treatment of patent Foramen ovale is considered medically necessary when using a device previously approved through the FDA Humanitarian Device Exemption and ALL of the following criteria are met:
1. There is history of cryptogenic stroke or transient ischemic attack due to presumed embolism through a PFO; and
2. Conventional conservative therapy (i.e. oral anticoagulation management) for cryptogenic stroke has failed or is contraindicated and direct closure is considered by the neurologist/ cardiologist to be medically appropriate.

Patent Ductus Arteriosus
The use of transcatheter closure device for the treatment of patent ductus arteriosus (PDA) considered medically necessary when using an FDA approved device.

Fenestration Following Fontan Procedure
The use of transcatheter closure device for the treatment of fenestrations following a Fontan procedure is considered medically necessary when using an FDA approved device.

EXCLUSIONS: The Plan does NOT provide coverage for the use of transcatheter closure of cardiac defects for migraine prophylaxis and for all other indications not listed above because it is considered experimental, investigational or unproven. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies.

The Plan does NOT provide coverage for the use of transmyocardial transcatheter closure of ventricular septal defects with implants because it is considered experimental, investigational or unproven. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Transcatheter Closure Devices for Cardiac Defects
The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

33675 Closure of multiple ventricular septal defects
33676 Closure of multiple ventricular septal defects; with pulmonary valvotomy or infundibular resection (acaynotic)
33677 Closure of multiple ventricular septal defects; with removal of pulmonary artery band, with or without gusset
93580 Percutaneous transcatheater closure of congenital interarterial communication (ie, fontan fenestration, atrial septal defect) with implant
93581 Percutaneous transcatheater closure of congenital ventricular septal defect with implant
93582 Percutaneous transcatheater closure of patent ductus arteriosus
93662 Intracardiac echocardiography during therapeutic/diagnostic intervention, including imaging supervision and interpretation.
C1817 Septal defect implant system, intracardiac
C1760 Closure device, vascular (implantable/insertable)


LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD’s and NCD’s will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:


Lock JE, “Patent Foramen Ovale is Indicted, but the Case Hasn’t Gone to Trial”, Circulation, 2000;101:838.


Geisinger Clinic Technology Assessment Committee approval July 11, 2001


ECRI, HTAIS Hotline. Transcatheter Closure of Atrial Septal Devices. 03/08/06


This policy will be revised as necessary and reviewed no less than annually.

Devised: 08/22/01

Revised: 9/01(coding); 8/02 Title change, additional device; 1/03 coding; 1/04 definition, coding; 1/05; 01/06 (revised indications and updated references); 01/07; 1/08 (criteria rev.); 2/10 (exclusion); 2/11 (indications)

Reviewed: 1/09, 2/12, 2/13, 2/14, 2/15, 2/16, 2/17, 2/18, 2/19, 2/20