BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 10/02/13
LAST REVIEW DATE: 11/26/13
LAST CRITERIA REVISION DATE: 11/26/13
ARCHIVE DATE:

TRANSCATHETER CLOSURE OF PATENT DUCTUS ARTERIOSUS

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

The ductus arteriosus is the vascular remnant of the left sixth aortic arch, connecting the main pulmonary artery to the aorta. A patent ductus arteriosus (PDA) is the persistent opening of the channel beyond its expected time of closure during the first few days of life. Catheter-based techniques have been developed to close PDAs to eliminate the need for general anesthesia, a thoracotomy and an extended hospital stay and convalescence associated with open surgical PDA closure. Devices include the Amplatzer™ Duct Occluder, Nit-Occlud™ PDA and the Gianturco Coil, also referred to as the Cook Embolization Coil.

TRANSCATHETER CLOSURE OF PATENT DUCTUS ARTERIOSUS (cont.)

Criteria:

- Transcatheter closure of patent ductus arteriosus using an FDA-approved device is considered ***medically necessary***. FDA-approved devices include:

  1. Amplatzer Duct Occluder
  2. Nit-Occlud PDA
  3. Gianturco Coil*

- Transcatheter closure of PDA using other non–FDA-approved devices is considered ***experimental or investigational*** based upon:

  1. Lack of final approval from the Food and Drug Administration, and
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  3. Insufficient evidence to support improvement of the net health outcome, and
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  5. Insufficient evidence to support improvement outside the investigational setting.

* The Gianturco Coil was marketed prior to 1976, when the FDA formally acquired regulatory authority over devices. Therefore, it has never undergone formal FDA approval but is available for clinical use.

Resources:

1. 7.01.61 BCBS Association Medical Policy Reference Manual. Transcatheter Closure of Patent Ductus Arteriosus. Re-issue date 10/10/2013, issue date 11/01/1997.

FDA Premarket Approval Database for Amplatzer Duct Occluder and Gianturco Coil*:

- FDA-approved indication: For the non-surgical closure of patent ductus arteriosus (PDA).

FDA Premarket Approval Database for Nit-Occud PDA:

- FDA-approved indication: For the percutaneous transcatheter closure of small to moderate patent ductus arteriosus with a minimum angiographic diameter less than 4 mm.

* The Gianturco Coil was marketed prior to 1976, when the FDA formally acquired regulatory authority over devices. Therefore, it has never undergone formal FDA approval but is available for clinical use.