MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

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TRANSCATHETER MITRAL VALVE REPAIR

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:

Transcathether mitral valve (MV) repair has been investigated as an alternative to surgical therapy for mitral regurgitation. Mitral regurgitation is a common valvular heart disease that can result from either a primary structural abnormality of the mitral valve complex or a dilated left ventricle due to ischemic or dilated cardiomyopathy, which leads to secondary dilatation of an anatomically normal mitral valve. Surgical therapy may be underutilized, particularly in individuals with multiple comorbidities. Transcatheter approaches are performed on the beating heart without the need for cardiopulmonary bypass. Approaches to MV repair include direct leaflet repair; repair of the mitral annulus via direct annuloplasty or through indirect approaches based on the annulus's proximity to the coronary sinus.

Devices include the MitraClip® Clip Delivery System, Carillon® Mitral Contour System™, Monarc™, Mitralign Percutaneous Annuloplasty System, Accucinch® System, enCorTC™, Cardioband™ Annuloplasty System, Endovalve™, CardiAQ™ and the Cardiovalve.

TRANSCATHETER MITRAL VALVE REPAIR (cont.)

Criteria:

- Transcatheter mitral valve repair is considered ***experimental or investigational*** based upon:

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

Resources:

1. 2.02.30 BCBS Association Medical Policy Reference Manual. Transcatheter Mitral Valve Repair. Issue date 07/10/2014.