blue of california

Medical Policy

Transcatheter Aortic Valve Replacement for Aortic Stenosis	
Type: Medical Necessity and Investigational / Experimental	**Policy Specific Section:** Surgery
Original Policy Date: March 30, 2012	**Effective Date:** March 7, 2013

Definitions of Decision Determinations

Medically Necessary: A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental: A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Description

Transcatheter aortic valve replacement (TAVR), also known as transcatheter aortic valve implantation (TAVI), is an alternative treatment for patients with severe aortic stenosis (AS), who have multiple medical comorbidities, which is indicative of high risk, and often prohibitive for more conventional surgery.

The procedure is performed percutaneously, most often through the transfemoral artery approach. It can also be done through the subclavian artery approach and transapically using mediastinoscopy. Balloon valvuloplasty is first performed in order to open up the stenotic area. This is followed by passage of a bioprosthetic artificial valve across the native aortic valve. The valve is initially compressed to allow passage across the native valve and is then expanded and secured to the underlying aortic-valve annulus. The procedure is performed on the beating heart without the need for cardiopulmonary bypass typically.

Policy

Transcatheter aortic valve replacement (TAVR), performed via the transfemoral or transapical approach, may be considered **medically necessary** for patients with aortic stenosis when **all** the following conditions are present:

- Calcified aortic annulus and severe aortic valve stenosis defined by **one or more** of the following criteria:
  - An aortic valve area of less than 0.8 cm^2
  - A mean aortic valve gradient greater than 40 mm Hg
  - A jet velocity greater than 4.0 m/sec
- NYHA [New Your Heart Association] heart failure Class II, III or IV symptoms
- Left ventricular ejection fraction >20%
- Documentation demonstrates **either** of the following situations:
  - Patient is not an operable candidate for open surgery as clinically determined by two cardiac surgeons
  - Patient is an operable candidate but is at high risk for open surgery (see Policy Guidelines)

Transcatheter aortic valve replacement is considered **investigational** for all other indications, including but not limited to:

- Patients with a degenerated bio-prosthetic valve ("Valve-in-Valve" implantation)
- Procedures performed via the transaxillary, transiliac, transaortic, or other approaches

Policy Guideline

New York Heart Association (NYHA) classifications:

- I Asymptomatic heart disease
- II Comfortable at rest; symptomatic with normal activity
- III Comfortable at rest; symptomatic with less than normal activity
- IV Symptomatic at rest

Criteria committee, NYHA, Inc: Diseases of the Heart and Blood Vessels, 6th edition, Little Brown, Boston 1964.

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High Risk for Open Surgery:

The U.S. Food and Drug Administration (FDA) definition of high risk for open surgery is defined by either of the following:

- Society of Thoracic Surgeons (STS) predicted operative risk score of >/= 8%; or
- Judged by a heart team, which includes an experienced cardiac surgeon and a cardiologist, to have an expected mortality risk of >/= 15% for open surgery

An online STS Risk Calculator can be found at URL address:
http://riskcalc.sts.org/STSWebRiskCalc261/de.aspx

Coding:

Effective in 2013, there are category I CPT codes for this procedure. These codes specify the surgical approach used for the TAVR/TAVI procedure:

- 33361: Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve percutaneous femoral artery approach
- 33362: Open femoral artery approach
- 33363: Open axillary artery approach
- 33364: Open iliac artery approach
- 33365: Transaortic approach (e.g., median sternotomy, mediastinotomy)
- 33366: Transapical exposure (e.g., left thoracotomy) (new code 1/1/14)

There is also a category III CPT code specific to the open thoracic approach:

- 0318T: Implantation of catheter-delivered prosthetic aortic heart valve, open thoracic approach, (e.g., transapical, other than transaortic)

The following CPT codes may be requested in addition to the primary procedure CPT codes above:

- 33367: Cardiopulmonary bypass support with percutaneous peripheral arterial and venous cannulation (e.g., femoral vessels) (List separately in addition to code for primary procedure)
- 33368: Cardiopulmonary bypass support with open peripheral arterial and venous cannulation (e.g., femoral, iliac, axillary vessels) (List separately in addition to code for primary procedure)
- 33369: Cardiopulmonary bypass support with central arterial and venous cannulation (e.g., aorta, right atrium, pulmonary artery) (List separately in addition to code for primary procedure)

Centers for Medicare & Medicaid Services (CMS)

On February 2, 2012 CMS proposed guidelines for transcatheter aortic valve replacement (TAVR). These recommendations are the result of collaboration between CMS, and the United States Food and Drug Administration (FDA), the Agency for Healthcare Research and Quality, the American College of Cardiology, the Society of Thoracic Surgeons and Edwards Lifesciences, Inc.

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Included below are the CMS specific requirements for both the facility and professional performing the TAVR procedure:

TAVR is covered for the treatment of severe symptomatic aortic valve stenosis only, when all of the following five conditions are met.

- The procedure is furnished for a FDA approved indication, with a complete valve and implantation system that has received FDA premarket approval (PMA) for this indication
- Two cardiac surgeons have, according to the pivotal PMA trial's protocol, evaluated the patient's suitability for open valve replacement surgery
- The procedure is furnished in a facility that meets the following institutional requirements:
    - For centers without previous PMA clinical trial TAVR experience
        - Surgical program requirements:
            - ≥50 total aortic valve replacement (AVR) procedures/year, including ten patients with STS (Society of Thoracic Surgeons) Score six
            - ≥two institutionally based cardiac surgeons
        - Interventional program requirements:
            - ≥400 caths/150 PCI's (percutaneous interventions) per year
            - ≥15 left sided structural endovascular aneurysm repair, thoracic endovascular aortic repair, etc. interventions per year
    - For centers with previous PMA clinical trial TAVR experience:
        - Participation in ongoing TAVR programs, either randomized controlled trials (RCTs) or post approval study (PAS)
        - Experience with ≥30 TAVR procedures and ≥ 20/year
        - TAVR program requirements:
            - ≥20 procedures/year OR ≥40 procedures/two years
            - 30 day all cause mortality ≤15%
            - 30 day neurologic events ≤15%
            - ≥90% institutional follow up of patients
            - ≥60% one year survival for non-operable patients
    - For all centers, with or without previous PMA clinical trial TAVR experience:
        - Participation in a prospective national TAVR study for ongoing enrollment and follow up of all TAVR patients
        - Commitment to Heart Team concept
- The procedure is performed by physicians with the following qualifications and experience:
    - Surgeon requirements:
        - Board Certified/Eligible in Cardiovascular Surgery

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        - Professional experience with:
            - ≥100 AVR/career including ten high risk patients; OR
            - ≥25 AVR/year or 50 AVR in two years; AND
            - ≥20 in the last year prior to TAVR
    - Interventionalist requirements
        - Operators must be Board Certified/Eligible in Interventional Cardiology
        - Professional experience with 50 structural heart disease procedures
- The patient is enrolled in, and the treating physician team is participating in a prospective national registry that consecutively enrolls TAVR patients and tracks at least the following outcomes at the patient data level for a period of at least five years:
    - Major stroke
    - All cause mortality
    - Minor stroke/ TIA
    - Major vascular events
    - Acute kidney injury
    - Repeat aortic valve procedures
    - Quality of life measures

The registry must be designed to permit identification and analysis of patient, practitioner and facility level factors that predict patient risk for these outcomes. The patient must have, after being informed of the reported risks of TAVR and reasonable alternative management strategies, given informed consent.

Internal Information

There is an MD Determination Form for this Medical Policy. It can be found on the following Web page:
http://myworkpath.com/healthcareservices/MedicalOperations/PSR_Determination_Pages.htm

Documentation Required for Clinical Review
• History and physical including: o NYHA heart failure classification o Reason for procedure o Severity of aortic stenosis • Consultation report(s) o Risk factors for open surgery o Society of Thoracic Surgeons (STS) predicted operative risk score or expected

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mortality risk for open surgery (if applicable)
  - Surgical approach planned (e.g., transfemoral, transapical)
  - Two cardiothoracic surgeons
- Echocardiogram results (within the last six months)
- Other cardiovascular studies if applicable

Post Service

- Operative report

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.

Click here to view the appendix for this policy

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