

POLICY TITLE	TRANSCATHETER AORTIC-VALVE IMPLANTATION FOR AORTIC STENOSIS
POLICY NUMBER	MP-1.135

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I. POLICY

Transcatheter aortic valve replacement, performed via the transfemoral approach, is considered **medically necessary** for patients with aortic stenosis when all of the following conditions are present:

- Severe aortic stenosis* with a calcified aortic annulus;
- NYHA heart failure Class II, III or IV symptoms;
- Left ventricular ejection fraction >20%; AND
- Patient is not an operable candidate for open surgery, as judged by at least two cardiovascular specialists (cardiologist and/or cardiac surgeon) ; or patient is an operable candidate but is at high risk for open surgery (see Policy Guidelines).

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

- Severe aortic stenosis (see Policy Guidelines) with a calcified aortic annulus;
- NYHA heart failure Class II,III or IV symptoms;
- Left ventricular ejection fraction >20%; AND
- 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

There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure for these indications.

POLICY TITLE	TRANSCATHETER AORTIC-VALVE IMPLANTATION FOR AORTIC STENOSIS
POLICY NUMBER	MP-1.135

POLICY GUIDELINES

Severe aortic stenosis is defined by one or more of the following criteria:

- An aortic valve area of less than 0.8 cm²
- A mean aortic valve gradient greater than 40 mmHg
- A jet velocity greater than 4.0 m/sec

FDA definition of high risk for open surgery:

- Society of Thoracic Surgeons 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.

II. PRODUCT VARIATIONS

[N] = No product variation, policy applies as stated

[Y] = Standard product coverage varies from application of this policy, see below

[N] Capital Cares 4 Kids

[N] PPO

[N] HMO

[Y] SeniorBlue HMO*

[Y] SeniorBlue PPO*

[N] Indemnity

[N] SpecialCare

[N] POS

[Y] FEP PPO**

* Refer to Centers for Medicare and Medicaid (CMS) [National Coverage Determination \(NCD\) Transcatheter Aortic Valve Replacement \(TAVR\)\(20.32\)](#) for coverage indications, specific hospital and heart team criteria, and for uses that are not expressly listed as an FDA-approved indication when performed within a clinical study. Effective for services performed on or after **May 1, 2012**, the Centers for Medicare and Medicaid Services (CMS) issued a National Coverage Determination (NCD) covering for Transcatheter Aortic Valve Replacement (TAVR) under Coverage with Evidence Development (CED). When the procedure is furnished for the treatment of symptomatic aortic stenosis and according to an FDA-approved indication for use with an approved device, CED requires that each patient be entered into a qualified national registry. In addition, prior to receiving TAVR, face-to-face examinations of the patient are required by two cardiac surgeons to evaluate the patient's suitability for TAVR. The NCD lists criteria for the physician, operators, and hospitals that must be met prior to beginning a TAVR program; and after a TAVR program is established.

For indications that are not approved by the FDA, patients must be enrolled in qualifying clinical studies. The clinical study must address pre-specified research questions, adhere to standards of scientific integrity, and be approved by CMS. TAVR is not covered for patients in whom

POLICY TITLE	TRANSCATHETER AORTIC-VALVE IMPLANTATION FOR AORTIC STENOSIS
POLICY NUMBER	MP-1.135

existing co-morbidities would preclude the expected benefit from correction of the aortic stenosis.

** Refer to FEP Medical Policy Manual MP-7.01.134 Transcatheter aortic-valve Implantation for Aortic Stenosis. The FEP Medical Policy manual can be found at:
<http://bluewebportal.bcbs.com/landingpagelevel3/504100?docId=23980>

III. DESCRIPTION/BACKGROUND

Transcatheter aortic valve implantation (TAVI) is a potential alternative treatment for patients with severe aortic stenosis. Many patients with aortic stenosis are very elderly and/or have multiple medical comorbidities, thus indicating a high-risk, often prohibitive, for surgery. This procedure is being evaluated as an alternative to open surgery for high-risk patients with aortic stenosis and as an alternative to nonsurgical therapy for patients with a prohibitive risk for surgery.

Aortic stenosis

Aortic stenosis is defined as narrowing of the aortic valve opening, resulting in obstruction of blood flow from the left ventricle into the ascending aorta. Progressive calcification of the aortic valve is the most common etiology in North America and Europe, while rheumatic fever is the most common etiology in developing countries. (1) Congenital abnormalities of the aortic valve, most commonly a bicuspid valve, increase the risk for aortic stenosis, but aortic stenosis can also occur in a normal aortic valve. Risk factors for calcification of a congenitally normal valve mirror those for atherosclerotic vascular disease, including advanced age, male gender, smoking, hypertension, and hyperlipidemia. (1) Thus, the pathogenesis of calcific aortic stenosis is thought to be similar to that of atherosclerosis, i.e., deposition of atherogenic lipids and infiltration of inflammatory cells, followed by progressive calcification.

The natural history of aortic stenosis involves a long asymptomatic period, with slowly progressive narrowing of the valve until the stenosis reaches the severe stage. At this time, symptoms of dyspnea, chest pain, and/or dizziness/syncope often occur and the disorder progresses rapidly. Treatment of aortic stenosis is primarily surgical, involving replacement of the diseased valve with a bio-prosthetic or mechanical valve by open heart surgery.

Burden of illness

Aortic stenosis is a relatively common disorder of elderly patients and is the most common acquired valve disorder in the U.S. Approximately 2-4% of individuals older than 65 years of age have evidence of significant aortic stenosis, (1) increasing up to 8% of individuals by age 85 years. (2) In the Helsinki Aging Study, a population-based study of 501 patients aged 75-86 years, the prevalence of severe aortic stenosis by echocardiography was estimated to be 2.9%. (3) In the U.S., more than 50,000 aortic valve replacements are performed annually due to severe aortic stenosis.

Aortic stenosis does not cause substantial morbidity or mortality when the disease is mild or moderate in severity. By the time it reaches the severe stage, there is an untreated mortality rate

POLICY TITLE	TRANSCATHETER AORTIC-VALVE IMPLANTATION FOR AORTIC STENOSIS
POLICY NUMBER	MP-1.135

of approximately 50% within 2 years. (4) Open surgical repair is an effective treatment for reversing aortic stenosis, and artificial valves have demonstrated good durability for periods up to 20 years. (4) However, these benefits are accompanied by a perioperative mortality of approximately 3-4% and substantial morbidity, (4) both of which increase with advancing age.

Unmet needs

Many patients with severe, symptomatic aortic stenosis are poor operative candidates. Approximately 30% of patients presenting with severe aortic stenosis do not undergo open surgery due to factors such as advanced age, advanced left ventricular dysfunction, or multiple medical comorbidities. (5) For patients who are not surgical candidates, medical therapy can partially alleviate the symptoms of aortic stenosis but does not affect the underlying disease progression. Percutaneous balloon valvuloplasty can be performed, but this procedure has less than optimal outcomes. (6) Balloon valvuloplasty can improve symptoms and increase flow across the stenotic valve but is associated with high rates of complications such as stroke, myocardial infarction (MI), and aortic regurgitation. In addition, restenosis can occur rapidly, and there is no improvement in mortality. As a result, there is a large unmet need for less invasive treatments for aortic stenosis in patients who are at increased risk for open surgery.

Transcatheter aortic valve implantation (TAVI)

TAVI has been developed in response to this unmet need and is intended as an alternative treatment for patients in whom surgery is not an option due to prohibitive surgical risk or for patients who are at high risk for open 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.

There are at least two transcatheter aortic valve devices being tested. The Edwards SAPIEN heart-valve system™ (Edwards Lifesciences, Irvine, CA) is a tri-leaflet bioprosthetic porcine valve that is contained within a stainless steel frame. This device has been commercially available in Europe since 2007 but has not yet received U.S. Food and Drug Administration (FDA) approval in the U.S. There is currently a next generation version of this valve in testing, called the SAPIEN XT™ (Edwards Lifesciences, Irvine, CA), which has been redesigned with the intention of reducing procedural complications.

The Medtronic CoreValve ReValving System™ is a second transcatheter valve system under testing. This device is a porcine bioprosthetic valve that is sewn within a self-expanding nitinol frame. It is inserted via the transfemoral artery approach and has also been inserted via the subclavian artery approach. This device has also been approved for use in Europe since 2007 but has not yet received FDA approval in the U.S.

POLICY TITLE	TRANSCATHETER AORTIC-VALVE IMPLANTATION FOR AORTIC STENOSIS
POLICY NUMBER	MP-1.135

Regulatory Status

The Sapien Transcatheter Heart Valve System™ (Edwards LifeSciences, Irvine, CA) received FDA approval in November 2011. Approval was granted for patients with severe aortic stenosis who are not eligible for open-heart procedures and have a calcified aortic annulus. The product labeling also advises that a heart surgeon should be involved in determining whether a patient is an acceptable candidate for transcatheter valve replacement. Exclusion criteria are patients who are candidates for an open procedure, patients with congenital heart abnormalities, patients with an infection in the heart, and/or cannot tolerate anticoagulation/antiplatelet therapy post-implantation.

IV. DEFINITIONS

N/A

V. BENEFIT VARIATIONS

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital for benefit information.

VI. DISCLAIMER

Capital's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VII. REFERENCES

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CMS [Website]: <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=355&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=Pennsylvania&KeyWord=aortic+valve+replacement&KeyWordLookUp=Title>

POLICY TITLE	TRANSCATHETER AORTIC-VALVE IMPLANTATION FOR AORTIC STENOSIS
POLICY NUMBER	MP-1.135

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POLICY TITLE	TRANSCATHETER AORTIC-VALVE IMPLANTATION FOR AORTIC STENOSIS
POLICY NUMBER	MP-1.135

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VIII. CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

CPT Codes ®							
33361	33362	33363	33364	33365	33366	33367	33368
33369							

MEDICAL POLICY

POLICY TITLE	TRANSCATHETER AORTIC-VALVE IMPLANTATION FOR AORTIC STENOSIS
POLICY NUMBER	MP-1.135

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ICD-9-CM Procedure Code*	Description
35.05	Endovascular replacement of aortic valve (new code effective 10/1/11)
35.22	Replacement of heart valve, other replacement of aortic valve

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

ICD-9-CM Diagnosis Code*	Description
395.0 – 395.9	Rheumatic aortic stenosis
396.0 – 396.9	Mitral valve stenosis and aortic valve stenosis
424.1	Aortic Valve disorders
425.11	Hypertrophic obstructive cardiomyopathy
428.0 - 428.9	Congestive Heart Failure
440.0	Arteriosclerosis of Aorta

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

The following ICD-10 diagnosis codes will be effective October 1, 2014:

ICD-10-CM Diagnosis Code*	Description
G71.2	Congenital myopathies
I06.1	Rheumatic aortic insufficiency
I06.2	Rheumatic aortic stenosis with insufficiency
I06.8	Other rheumatic aortic valve diseases
I08.0	Rheumatic disorders of both mitral and aortic valves
I08.8	Other rheumatic multiple valve diseases
I35.0 – I35.9	Other nonrheumatic aortic valve disorders
I42.1	Obstructive hypertrophic cardiomyopathy
I50.20 – I50.23	Unspecified systolic (congestive) heart failure

MEDICAL POLICY

POLICY TITLE	TRANSCATHETER AORTIC-VALVE IMPLANTATION FOR AORTIC STENOSIS
POLICY NUMBER	MP-1.135

ICD-10-CM Diagnosis Code*	Description
I50.30 – I50.33	Unspecified diastolic (congestive) heart failure
I50.40 – I50.432	Unspecified combined systolic (congestive) and diastolic (congestive) heart failure
I50.9	Heart failure, unspecified
I70.0	Atherosclerosis of aorta

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

IX. POLICY HISTORY

MP-1.135	CAC 6/26/12 New policy- Adopt BCBSA -Transcatheter aortic valve replacement, performed via the transfemoral approach, is considered medically necessary for patients with aortic stenosis when specific criteria have been met. 8/13/12 Medicare variation added.
	12/26/2012- New codes added-skb
	CAC 7/30/13 Minor revision, Medically necessary indications added for patients who are at high risk for open surgery using the transfemoral approach, and patients who are at high risk for open surgery using the transapical approach. Investigational statement added for treatment of degenerated bio-prosthetic valve or failed TAVI (Valve-in-Valve approach), and for vascular approaches other than transfemoral or transapical. References updated. Guidelines added. FEP variation added. Policy coded.
	12/19/2013- New 2014 Code updates made.

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