Transcatheter Aortic-Valve Implantation for Aortic Stenosis

I. Policy

University Health Alliance (UHA) will reimburse for transcatheter aortic-valve implantation for aortic stenosis when determined to be medically necessary and within the medical criteria guidelines (subject to limitations and exclusions) indicated below.

II. Background

Many patients with severe aortic stenosis and coexisting conditions are not candidates for surgical replacement of the aortic valve. Transcatheter aortic-valve implantation (TAVI) is a potentional alternative for high-risk patients with severe aortic stenosis.

The development and adoption of this technique has been lengthy, complex, and the subject of FDA scrutiny and guidance. It is anticipated that indications and contraindications will continue to evolve. Accordingly, coverage for transcatheter aortic-valve implantation for aortic stenosis may be subject to CMS amendment and payment policy revision.

III. Criteria/Guidelines

A. Transcatheter aortic valve replacement, performed via the transfemoral approach, is covered (subject to Limitations / Exclusions and Administrative Guidelines) for patients with aortic stenosis when all of CMS coverage conditions are met. These include, but are not limited to:

1. Severe aortic stenosis (defined below, Section III.A.4) with a calcified aortic annulus; and
2. Left ventricular ejection fraction greater than 20%; and
3. NYHA heart failure Class II, III or IV symptoms (See below for class definitions); and
4. Patient is not an operable candidate for open surgery, as judged by at least two cardiovascular specialists (cardiologist and/or cardiac surgeon); or
5. Patient is an operable candidate but is at high or intermediate risk for open surgery defined as:
    a. High risk for open surgery:
        i. Society of Thoracic Surgeons predicted operative risk score of 8% or higher; or
        ii. Judged by a valve surgeon and a structural cardiologist to have an expected mortality risk of 15% or higher.
    b. Intermediate risk for open surgery:
        i. Society of Thoracic Surgeons predicted operative risk score of 3% to 7%.
6. Transcatheter aortic valve replacement is performed with an U.S. Food and Drug Administration (FDA)-approved transcatheter heart valve system, performed via an approach consistent with the device's FDA-approved labeling,

B. Transcatheter aortic valve replacement with a transcatheter heart valve system approved for use for repair of a degenerated bioprosthetic valve is covered when all of the following conditions are present:

1. Failed (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic valve; AND
2. New York Heart Association heart failure class II, III or IV symptoms; AND

3. Left ventricular ejection fraction greater than 20%; AND
4. Patient is not an operable candidate for open surgery, as judged by at least 2 cardiovascular specialists (cardiologist and/or cardiac surgeon); OR
5. Patient is an operable candidate but is at high risk for open surgery defined as:
    a. Society of Thoracic Surgeons predicted operative risk score of 8% or higher; or
    b. Judged by a heart team, which includes an experienced cardiac surgeon and a cardiologist, to have an expected mortality risk of 15% or higher for open surgery.

IV. Limitations/Exclusions/Definitions

A. Transcatheter aortic valve replacement is not covered for all other indications. Devices without FDA approval are not covered.

B. Severe aortic stenosis is defined by one or more of the following criteria:
    1. An aortic valve area of less than 0.8 cm^2
    2. A mean aortic valve gradient greater than 40 mmHg
    3. A jet velocity greater than 4.0 m/sec

C. For the use of the SAPIEN or CoreValve devices, severe aortic stenosis is defined by the presence of one or more of the following criteria:
    1. An aortic valve area of less than or equal to 1 cm^2
    2. An aortic valve area index of less than or equal to 0.6 cm^2/m^2
    3. A mean aortic valve gradient greater than or equal to 40 mm Hg
    4. A peak aortic-jet velocity greater than or equal to 4.0 m/s

D. NYHA heart failure Class definitions:

Class	Description
I	Patients with cardiac disease but resulting in no limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea or anginal pain.
II	Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea or anginal pain.
III	Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea or anginal pain.
IV	Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of heart failure or anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort increases.

NOTE:

This UHA payment policy is a guide to coverage, the need for prior authorization and other administrative directives. It is not meant to provide instruction in the practice of medicine and it should not deter a provider from expressing his/her judgment.

Even though this payment policy may indicate that a particular service or supply is considered covered, specific provider contract terms and/or member's individual benefit plans may apply, and this policy is not a guarantee of payment. UHA reserves the right to apply this payment policy to all UHA companies and subsidiaries.

UHA understands that opinions about and approaches to clinical problems may vary. Questions concerning medical necessity (see Hawaii Revised Statutes §432E-1.4) are welcome. A provider may

request that UHA reconsider the application of the medical necessity criteria in light of any supporting documentation.

V. Administrative Guidelines

A. Prior authorization is not required. Documentation of institution based procedure planning must exist for UHA's review upon request for medical necessity determination.

B. Include the following documentation:

1. History and physical
2. Documentation indicating that the patient is not an operable candidate for open surgery, confirmed by two cardiovascular specialists
3. Diagnostic studies confirming severe aortic stenosis

C. Applicable codes:

Inpatient Procedure Code	Description
35.05	Endovascular replacement of aortic valve

CPT Code	Description
33361	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; percutaneous femoral artery approach
33362	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open femoral artery approach
33363	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open axillary artery approach
33364	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; open iliac artery approach
33365	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transaortic approach (e.g., median sternotomy, mediastinotomy)

VI. Policy History

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