

Transcatheter Aortic Valve Replacement

Policy ID:	HHO-DE-MP-1125
Approved By:	Highmark Health Options – Market Leadership
Provider Notice Date:	12/15/2021; 03/01/2023
Original Effective Date:	01/15/2022; 04/01/2023
Annual Approval Date:	10/08/2021; 08/24/2022
Last Revision Date:	10/08/2021; 08/24/2022
Products:	Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 6

Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under the medical-surgical benefits of the Company's Medicaid products for medically necessary benefits.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan and Health Plan Plus members.

POLICY POSITION

Prior authorization is required.

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

TAVR performed for severe aortic stenosis, using a United States Food and Drug Administration (U.S. FDA)-approved Transcatheter Heart Valve System, may be considered medically necessary when ALL of the following criteria are met:

- The individual has aortic stenosis with a calcified aortic annulus, as defined by ONE or MORE of the following criteria:
 - An aortic valve area of less than 1.0 cm²; or
 - An aortic valve area index of less than or equal to 0.6 cm² /m²; or
 - A mean aortic valve gradient greater than 40 mmHg; or
 - A peak aortic-jet velocity greater than 4.0 m/sec; and
- The individual has New York Heart Association (NYHA) Classification II, III, or IV symptoms (see table below); and
- Left ventricular ejection fraction greater than 20%; and
- Individual is not an operable candidate for open surgery, as determined by at least two (2) cardiovascular specialists (cardiologist and/or cardiac surgeon); or individual is an operable candidate but is at intermediate risk or high risk for open surgery; or individual is at low to high risk for death and complications with open-heart surgery, and
- The procedure is being performed by a professional provider and at a facility that meets the recommendations for performing TAVR, as set forth in the Credentialing Recommendations for Heart Valve Replacement Procedure, established in collaboration with the following cardiovascular specialty societies: the American College of Cardiology Foundation (ACCF), the Society for Cardiovascular Angiography and Interventions (SCAI), the American Association for Thoracic Surgery (AATS), and the Society of Thoracic Surgeons (STS).

TAVR with a transcatheter heart valve system approved for use for repair of a degenerated bioprosthetic valve may be considered medically necessary when ALL of the following conditions are present:

- Failed (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic valve; and
- NYHA heart failure class II, III, or IV symptoms; and
- Left ventricular ejection fraction greater than 20%; and
- The individual is not an operable candidate for open surgery, as determined by at least two (2) cardiovascular specialists (cardiologist and/or cardiac surgeon) or individual is an operable candidate but is at low to high risk for death and complications with open-heart surgery.

TAVR procedures not meeting the criteria as indicated in this policy is considered not medically necessary.

NEW YORK HEART ASSOCIATION (NYHA) CLASSIFICATION OF HEART FAILURE

Class	Description
Class I	No limitation of physical activity. Ordinary physical activity does not cause undue breathlessness, fatigue, or palpitations.
Class II	Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in undue breathlessness, fatigue, or palpitations.
Class III	Marked limitation of physical activity. Comfortable at rest, but less than ordinary physical activity result in undue breathlessness, fatigue, or palpitations.
Class IV	Unable to carry on any physical activity without discomfort. Symptoms at rest can be present. If any physical activity is undertaken, discomfort is increased.

ELIGIBLE PROCEDURE CODES

CPT Codes	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).
33366	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; transapical exposure (e.g., left thoracotomy).
33367	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; cardiopulmonary bypass support with percutaneous peripheral arterial and venous cannulation (e.g., femoral vessels) (list separately in addition to code for primary procedure).
33368	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; 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	Transcatheter aortic valve replacement (TAVR/TAVI) with prosthetic valve; 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).
93591	Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, aortic valve.

ELIGIBLE DIAGNOSIS CODES FOR PROCEDURE CODES 33361, 33362, 33363, 33364, 33365, 33366 AND 93591

Codes						
I06.0	I06.2	I35.0	I35.1	I35.2	I35.8	I35.9

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POLICY UPDATE HISTORY

10/08/2021	Approved in medical policy committee
08/24/2022	Annual review; approved in medical policy committee
09/13/2022	Approved in QI-UM
10/10/2022	Approved in Governance