



**CorHealth
Ontario**

*Advancing cardiac, stroke
and vascular care*

Ontario Transcatheter Aortic Valve Implantation (TAVI) Patient Eligibility Criteria Guidelines & Facility Quality Criteria

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About CorHealth Ontario

As of June 22, 2017, we are CorHealth Ontario, an organization formed by the merger of the Cardiac Care Network of Ontario and the Ontario Stroke Network, with an expanded mandate spanning cardiac, stroke and vascular through the entire course of care including secondary prevention, rehabilitation and recovery. CorHealth Ontario proudly advises the Ministry of Health and Long - Term Care (MOHLTC), Local Health Integration Networks, hospitals, and care providers to improve the quality, efficiency, accessibility and equity of cardiac, stroke and vascular services for patients across Ontario. For more information, [visit corhealthontario.ca](http://visit.corhealthontario.ca).

Ontario Transcatheter Aortic Valve Implantation (TAVI) Patient Eligibility Criteria Guidelines

Transcatheter aortic valve implantation (TAVI) is an established therapy in the treatment of symptomatic severe aortic stenosis (AS). In 2016 Ontario Health Technology Advisory Committee (OHTAC) recommended TAVI should be considered as a viable treatment option in patients who are not candidates for surgical aortic valve replacement (SAVR), or patients for whom SAVR is deemed to be high risk¹.

The role of TAVI has continued to evolve and in March 2020 OHTAC recommended TAVI should be considered as a viable treatment option in patients who are at intermediate surgical risk. Later that year in November 2020 OHTAC recommended TAVI should be considered as a viable treatment option in patients who are at low surgical risk.

Determination of patient acceptance for the procedure will be made by the hospital's designated Interdisciplinary Heart Team, whereby criteria and factors outlined in the following sections are considered. Patients should be evaluated by minimum a cardiac surgeon and cardiologist with knowledge and experience in both TAVI and SAVR², as well as appropriate subspecialties as determined by the Interdisciplinary Heart Team.

¹ TAVI for Treatment of Aortic Valve Stenosis: OHTAC Recommendation (2016)

² AATS/ACC/SCAI/STS Expert Consensus on Operator and Institutional Requirements for TAVR (2017)

Considerations in determining patients who are suitable for TAVI:

1. Symptomatic severe aortic stenosis (AS) with
 - a. metrics of valve anatomy, valve hemodynamics, and hemodynamic consequences consistent with (as defined in Appendix A):
 - i. high-gradient AS
 - ii. low-flow/low-gradient AS with reduced left ventricular ejection fraction (LVEF); or
 - iii. low-gradient AS with normal LVEF or paradoxical low-flow severe AS
 - b. severity of symptoms due to AS (angina, shortness of breath, syncope) deemed acceptable for valve intervention, as determined through shared decision making by the patient and the Interdisciplinary Heart Team.
2. Low, Intermediate, High or Inoperable Surgical Risk
3. Assessment by and agreement of the Interdisciplinary Heart Team, with explicit consideration of patient preference, elicited using a shared decision making framework.



Considerations in determining patients who are not suitable for TAVI:

1. Anatomic unsuitability of the valve or inability to access the valve
2. Patient is considered unlikely to experience an improvement in life expectancy and quality of life. Factors considered may include³:
 - ≥ 3 major organ system compromises not to be improved post-TAVI.
 - Severe frailty: ≥ 4 indices based on Katz index (independence in feeding, bathing, dressing, transferring, toileting, and urinary incontinence) and independence in ambulation (walk 5 m in < 6 s).
 - PARTNER TAVI score or FRANCE 2 TAVI score ≥ 8 (30-day mortality risk $>25\%$).
 - See Table 1 for additional medical comorbidities and factors which have been shown to predict poorer outcomes post-TAVI .

Table 1

Medical Comorbidity	Factors Specifically Associated with Futility ³
Chronic Lung disease	<ul style="list-style-type: none"> • 6 minute walk test < 150m • Oxygen dependency
Advanced Chronic Kidney Disease	<ul style="list-style-type: none"> • Dialysis dependence
Frailty	<ul style="list-style-type: none"> • >2 frailty indices (Katz activities of daily living + mobility status)
Cardiovascular Conditions	<ul style="list-style-type: none"> • LVEF$<30\%$ • Pre-capillary or combined pulmonary hypertension (mean pulmonary artery pressure $\# >25$mmHg) • Low trans-aortic gradient • Impaired contractile reserve • Low flow state (<35 mL/m²) • Organic severe mitral regurgitation
Additional factors for consideration ⁴	
<ul style="list-style-type: none"> • Peripheral artery disease • Cognitive functioning using objective techniques such as Mini Mental State Examination (MMSE), depression screen • Neurological disorders such as movement disorders or dementia • Advanced oncology conditions 	

³ Predicting TAVI Futility (Puri et. al., 2016)

⁴ American College of Cardiology Expert Consensus Decision Pathway for TAVR in AS Management (2017)

Imaging Assessment of Anatomic/Functional Factors⁴

- TTE assessment of valve morphology (trileaflet, bicuspid, or unicuspid), valve calcification, leaflet motion, annular size and shape.⁴
- TTE assessment of valve function: maximum aortic velocity, mean aortic valve gradient, aortic valve area, stroke volume index, presence and severity of aortic regurgitation. Dobutamine stress echocardiography may be considered for severely reduced LV function and a low transaortic gradient.⁴
- TTE assessment of LV geometry and other cardiac findings: LVEF, regional wall motion; hypertrophy, diastolic function; pulmonary pressure estimate; mitral valve (MR, MS, MAC).
- Accurate measurement of annulus size by TAVI CTA*-gated contrast-enhanced CT thorax with multiphasic acquisition.⁴
- Aortic root measurements with gated contrast-enhanced CT thorax with multiphasic acquisition
- Assessment for coronary disease and thoracic anatomy with coronary angiography and non-gated thoracic CTA.⁴
- May consider carotid ultrasound or cerebrovascular MRI depending on clinical history.⁴
- Assess vascular access with imaging modality appropriate for patient renal function e.g. TAVI CTA*, contrast MRA, femoral angiography etc.⁴

*TAVI CTA: Unless otherwise noted, refers to a single arterial phase CTA of the chest, abdomen, and pelvis. Typically, the thorax is acquired using ECG-gated multiphase acquisition. At minimum acquisition and reconstruction should include end systole, usually between 30% and 40% of the R-R window. Given use of CT, the role in annular sizing prior to TAVI with TEE is limited. Peri-procedural use of TEE is limited to cases performed.

Note: Integration of measurements by both TEE and TTE shall be from a facility that meets CorHealth Ontario's Standards for Provision of Echocardiography in Ontario

⁴American College of Cardiology Expert Consensus Decision Pathway for TAVR in AS Management (2017)

Ontario Transcatheter Aortic Valve Implantation (TAVI) Facility Quality Criteria

Procedure Volumes Criteria

The hospital program must maintain the following:

- Minimum TAVI volume: 50 cases per year.
- Minimum SAVR volume: 40 cases per year.²
- Minimum vascular arterial intervention volume: 150 cases over prior 3 years.²
- Pacemaker capabilities²:
 - › Experienced and competent physicians for temporary and permanent pacemaker placement and management.
 - › On-site services should be available 24 hours/day and 7 days/week to handle conduction disturbances as a result of the TAVI procedure.



² AATS/ACC/SCAI/STS Expert Consensus on Operator and Institutional Requirements for TAVR (2017)

FACILITY CRITERIA

Criteria Description	Method of Evaluation
1. Catheterization Lab/ hybrid operating suite with fixed x-ray imaging	
Programs performing TAVI procedures require a cardiac catheterization lab/ hybrid operating suite with fixed x-ray imaging system with flat-panel fluoroscopy, offering quality imaging.	<p>Operating room/catheterization lab environment shall:</p> <ul style="list-style-type: none"> • Have sufficient space (approx. 800 sq ft), in a sterile environment, to accommodate necessary personnel, anaesthesia equipment, echocardiography machines, intra-aortic balloon pumps, and cardiopulmonary bypass machines.
2. Anaesthesia facilities	
Programs performing TAVI procedures shall ensure anaesthesia equipment, drugs and supplies meet the same standards as those for conventional operating theatres (Canadian Anesthesiologist Society).	<p>Anaesthesia facilities shall:</p> <ul style="list-style-type: none"> • Ensure standardized anaesthesia equipment is available and maintained as per the organization's standard operating procedures.
3. Access to imaging	
<p>Programs providing TAVI procedures are required to have access to:</p> <ul style="list-style-type: none"> • Transthoracic Echocardiography (TTE). • Transesophageal Echocardiography (TEE). • Vascular Ultrasound, Magnetic Resonance Angiography (MRA), Peripheral Angiography. • CT Lab, Multidetector Computed Tomography (MDCT). 	<p>Imaging services shall:</p> <ul style="list-style-type: none"> • Achieve CorHealth Ontario's certification in Standards for Provision of Echocardiography in Ontario • Include Cardiac Sonographers and Echocardiologist (Level 3 training) who have experience in valvular disease
4. Intensive Care Unit (ICU) Facilities	
Programs providing TAVI procedures will have access to a post-procedure Level 3 ICU.	<p>ICU facility shall:</p> <ul style="list-style-type: none"> • Ensure healthcare team members are experienced in managing patients who have undergone open-heart valve procedures.
5. Other facilities/services	
<ul style="list-style-type: none"> • On-site heart valve surgery program. • Perfusion services. • Renal replacement therapy. • Vascular surgery. • Peripheral vascular interventional expertise. • Physical space/setup for the TAVI clinic to support patient assessment. 	

CLINICAL SERVICES CRITERIA

Criteria Description

Method of Evaluation

6. Multidisciplinary Heart Team

Programs performing TAVI must have a functioning Interdisciplinary Heart Team in order to optimize patient outcomes. The interdisciplinary heart team is defined as all members of the program required from initial pre-procedural work-up, eligibility determination, procedural care, post-TAVI in-hospital care, and subsequent outpatient follow-up. The roles of each team member may vary by individual site, however sites will have specific documentation of each role and a documented process for determining patient eligibility.

Core Interdisciplinary Heart Team shall be composed of the following members:

Member	Responsibility
Cardiac Surgeon	Patient Eligibility/Overall Patient Care
Interventional Cardiologist	Patient Eligibility/Overall Patient Care
TAVI Care Coordinator	Patient Eligibility/Pre and Post-Procedural Patient Care
Imaging Specialist	Pre-procedural Diagnostic Evaluation
Echocardiologist	Pre and Post-procedural Diagnostic Evaluation
Cardiac Anesthesiologist	Procedural Patient Care
OR/Cath Lab Nurses	Procedural Patient Care

Core Interdisciplinary Heart Team shall have access to the following adjunct members as needed:

- Vascular Surgery
- Neurology
- Cardiology/Heart Failure Specialist
- Electrophysiology
- Internal Medicine
- Perfusionists
- Respiriology
- Nephrology
- Geriatrician
- DI/Medical Imaging
- Imaging Technicians
- Vascular Lab Technicians
- ICU/CVICU/CICU Nursing and Allied
- Health (Physiotherapy, Occupational Therapy, Pharmacy, Social Work, Chaplin)
- Other relevant members
- Nurse Practitioner
- Oncology

Interdisciplinary Heart Team shall:

- Determine patient eligibility through evaluation by both a cardiac surgeon and interventional cardiologist for each case. A documented process must be in place to ensure this co-evaluation is operationalized.
- Utilize the Ontario TAVI Patient Eligibility Criteria Guidelines to inform patient selection.
 - Commit to principles of shared decision making which may include:
 - Ensure patients and families are given comprehensive information on the various operative and non-operative treatment options
 - Ensure patient and family educational materials reflect an appropriate health literacy level
 - Ensure patients and families have direct access to representatives of each specialty
- Remain current with new and evolving evidence as it relates to TAVI.
- Utilize appropriate evidence based guidelines (where applicable) to inform decision making.
- Ensure opportunity to train and work together regularly.
- Engage in strategies to continuously improve team functions.
- Ensure protocol-driven standardized approaches to patient care, discharge planning, and follow-up which may include:
 - Utilize standardized care pathways that include optimization of Length of Stay (LOS)
 - Ensure assessment of patient readiness for discharge
 - Emphasize specific issues that would warrant immediate contact with the Heart Team
 - Arrange follow-up appointments as appropriate
 - Arrange for rehabilitation when deemed appropriate
 - Standardize communications with referring physicians

CLINICAL SERVICES CRITERIA

Criteria Description	Method of Evaluation
7. Hospital Administration	
Programs providing TAVI procedures will have a dedicated hospital administrator as part of the team.	Hospital Administrator shall: <ul style="list-style-type: none"> • Ensure all necessary infrastructure are in place to adequately support the TAVI program.
8. Training	
Programs providing TAVI procedures will ensure ongoing relevant training for the Interdisciplinary Heart Team.	Programs shall: <ul style="list-style-type: none"> • Ensure Interdisciplinary Heart Team remains up to date with new and evolving evidence as it relates to TAVI.
9. CorHealth Ontario Registry Participation	
Programs providing TAVI will engage in ongoing outcome evaluation.	Programs shall: <ul style="list-style-type: none"> • Participate in CorHealth Ontario Registry <ul style="list-style-type: none"> › Including all data elements required for quality monitoring as determined by CorHealth Ontario • Participate in ongoing evaluation to ensure volume criteria are maintained
10. Quality Improvement	
Programs providing TAVI procedures will engage in quality improvement processes.	Programs shall: <ul style="list-style-type: none"> • Participate in ongoing outcome measurement

Appendix A: Stages of Valvular Aortic Stenosis⁵

Stage	Definition	Valve Anatomy	Valve Hemodynamics	Hemodynamic Consequences	Symptoms
A	At risk of AS	<ul style="list-style-type: none"> Bicuspid aortic valve (or other congenital valve anomaly) Aortic valve sclerosis 	<ul style="list-style-type: none"> Aortic $V_{max} < 2$ m/s 	<ul style="list-style-type: none"> None 	<ul style="list-style-type: none"> None
B	Progressive AS	<ul style="list-style-type: none"> Mild-to-moderate leaflet calcification of a bicuspid or trileaflet valve with some reduction in systolic motion or Rheumatic valve changes with commissural fusion 	<ul style="list-style-type: none"> Mild AS: Aortic V_{max} 2.0–2.9 m/s or mean $\Delta P < 20$ mm Hg Moderate AS: Aortic V_{max} 3.0–3.9 m/s or mean ΔP 20–39 mm Hg 	<ul style="list-style-type: none"> Early LV diastolic dysfunction may be present Normal LVEF 	<ul style="list-style-type: none"> None
C: Asymptomatic severe AS					
C1	Asymptomatic severe AS	<ul style="list-style-type: none"> Severe leaflet calcification or congenital stenosis with severely reduced leaflet opening 	<ul style="list-style-type: none"> Aortic $V_{max} > 4$ m/s or mean $\Delta P > 40$ mm Hg AVA typically is ≤ 1.0 cm² (or AVAi ≤ 0.6 cm²/m²) Very severe AS is an aortic $V_{max} > 5$ m/s or mean $\Delta P \geq 60$ mm Hg 	<ul style="list-style-type: none"> LV diastolic dysfunction Mild LV hypertrophy Normal LVEF 	<ul style="list-style-type: none"> None: Exercise testing is reasonable to confirm symptom status
C2	Asymptomatic severe AS with LV dysfunction	<ul style="list-style-type: none"> Severe leaflet calcification or congenital stenosis with severely reduced leaflet opening 	<ul style="list-style-type: none"> Aortic $V_{max} \geq 4$ m/s or mean $\Delta P \geq 40$ mm Hg AVA typically ≤ 1.0 cm² (or AVAi ≤ 0.6 cm²/m²) 	<ul style="list-style-type: none"> LVEF $< 50\%$ 	<ul style="list-style-type: none"> None
D: Symptomatic severe AS					
D1	Symptomatic severe high-gradient AS	<ul style="list-style-type: none"> Severe leaflet calcification or congenital stenosis with severely reduced leaflet opening 	<ul style="list-style-type: none"> Aortic $V_{max} \geq 4$ m/s or mean $\Delta P \geq 40$ mm Hg AVA typically ≤ 1.0 cm² (or AVAi ≤ 0.6 cm²/m²) but may be larger with mixed AS/AR 	<ul style="list-style-type: none"> LV diastolic dysfunction LV hypertrophy Pulmonary hypertension may be present 	<ul style="list-style-type: none"> Exertional dyspnea or decreased exercise tolerance Exertional angina Exertional syncope or presyncope
D2	Symptomatic severe low-flow/low-gradient AS with reduced LVEF	<ul style="list-style-type: none"> Severe leaflet calcification with severely reduced leaflet motion 	<ul style="list-style-type: none"> AVA ≤ 1.0 cm² with resting aortic $V_{max} < 4$ m/s or mean $\Delta P < 40$ mm Hg Dobutamine stress echocardiography shows AVA ≤ 1.0 cm² with $V_{max} \geq 4$ m/s at any flow rate 	<ul style="list-style-type: none"> LV diastolic dysfunction LV hypertrophy LVEF $< 50\%$ 	<ul style="list-style-type: none"> HF Angina Syncope or presyncope
D3	Symptomatic severe low-gradient AS with normal LVEF or paradoxical low-flow severe AS	<ul style="list-style-type: none"> Severe leaflet calcification with severely reduced leaflet motion 	<ul style="list-style-type: none"> AVA ≤ 1.0 cm² with aortic $V_{max} < 4$ m/s or mean $\Delta P < 40$ mm Hg Indexed AVA ≤ 0.6 cm²/m² and Stroke volume index < 35 mL/m² Measured when patient is normotensive (systolic BP < 140 mm Hg) 	<ul style="list-style-type: none"> Increased LV relative wall thickness Small LV chamber with low stroke volume Restrictive diastolic filling LVEF $\geq 50\%$ 	<ul style="list-style-type: none"> HF Angina Syncope or presyncope

Appendix B: Acronyms and Abbreviations

AATS = American Association for Thoracic Surgery
ACC = American College of Cardiology
AHA = American Heart Association
AR = aortic regurgitation
AS = aortic stenosis
AV = atrioventricular
AVA = aortic valve area
AVAi = aortic valve area indexed to body surface area
AVR = aortic valve replacement
BP = blood pressure
CT = computed tomography
CTA = computed tomography angiography
ECG = electrocardiogram
FRANCE 2 = French Aortic National CoreValve and Edwards 2
HF = heart failure
LV = left ventricular
LVEF = left ventricular ejection fraction
MAC = mitral annular calcification
MR = mitral regurgitation
MRA = magnetic resonance angiogram
MS = mitral stenosis
PARTNER = Placement of Aortic Transcatheter Valves
SAVR = surgical aortic valve replacement
SCAI = Society for Cardiovascular Angiography and Interventions
STS = Society of Thoracic Surgeons
TAVI = transcatheter aortic valve implantation
TEE = transesophageal echocardiography
TTE = transthoracic echocardiography
 V_{\max} = maximum aortic velocity
 ΔP = pressure gradient

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