Technology Guidance

Transcatheter aortic valve implantation

for patients with symptomatic severe native aortic stenosis

Technology Guidance issued by the Agency for Care Effectiveness based on assessments made by the MOH Medical Technology Advisory Committee and recommendations of the Health Technology Advisory Council

Guidance Recommendations

Transcatheter aortic valve implantation (TAVI) is recommended for inclusion on the MOH Implant Subsidy List (ISL) for treatment of patients with symptomatic severe native aortic stenosis (AS) in line with the following criteria:

- ✓ TAVI may be considered for patients with symptomatic severe native AS who are inoperable or at high risk of mortality from surgical aortic valve replacement (SAVR) surgery and significant comorbidities.
- ✓ Patient selection should be carried out by a multidisciplinary heart team, which must at minimum include an interventional cardiologist and a cardiac surgeon. The team should determine the surgical mortality risk for each patient based on:
  - An estimated mortality risk of 8% or greater within 30 days of surgery, according to the Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) risk assessment; OR
  - Other patient characteristics where these conditions are clinically equivalent to inoperable or high risk (STS-PROM score ≥8%). These examples could include but are not limited to those listed in the Annex. Where appropriate, objective tools should be used to assess these characteristics.
- ✓ TAVI should be conducted by a multidisciplinary heart team that has met the applicable TAVI training and accreditation standards set by the institution.
- ✓ The TAVI procedure should be performed via transfemoral delivery, unless it is contraindicated or not feasible, in catheterisation labs or hybrid operating theatres equipped with early in-hospital access to cardiac and vascular surgical support for the emergency treatment of complications and subsequent patient care.

- ✓ Properly record details of final surgical risk assessments of all patients who receive TAVI including STS-PROM score, type of TAVI device and clinical outcomes. This is consistent with the standard arrangements in place for clinical governance and audit.

- ✓ TAVI should not be subsidised if the patient has received a prior SAVR or TAVI implant.

Funding status

Listed models on MOH ISL are recommended for subsidy when used in line with the abovementioned recommendations.

Published: 27 March 2026

Technology Evaluation

1.1. At the November 2020, March 2021 and March 2025 meetings, the MOH Medical Technology Advisory Committee ("the Committee") considered the evidence presented for the technology evaluation of transcatheter aortic valve implantation (TAVI) for treatment in patients with symptomatic severe native aortic stenosis (AS). This topic was later discussed in May 2025 by the Health Technology Advisory Council ("the Council"), an independent professional body that supports the MOH in determining if financial support for high-cost, high-impact health technologies is appropriate.

1.2. The Agency for Care Effectiveness (ACE) conducted the evaluation in consultation with clinical experts from public healthcare institutions. Published clinical and economic evidence for TAVI was considered in line with its registered indications.

1.3. The evidence was used to inform the deliberations around five core decision-making criteria:

- Clinical need of patients and nature of the condition;
- Clinical effectiveness and safety of the technology;
- Cost-effectiveness (value for money) – the incremental benefit and cost of the technology compared to existing alternatives;
- Estimated annual technology cost and the number of patients likely to benefit from the technology; and
- Organisational feasibility – the potential impact of adopting the technology, especially barriers for diffusion.

1.4. Additional factors, including social and value judgments, may also inform the funding considerations.

Assessments made by the MOH Medical Technology Advisory Committee (November 2020 and March 2021)

Clinical need

2.1. The Committee noted that symptomatic severe native AS is a chronic condition where the aortic valve is narrowed. This critically obstructs blood flow from the left ventricle to the aorta and can lead to heart failure. Only aortic valve replacement can treat or alter the disease course. Patients with symptomatic severe AS who do not undergo aortic valve replacement have a poor prognosis.

2.2. The Committee noted that patients with symptomatic severe native AS can be stratified by their estimated risk of surgical mortality, to weigh the risks of the intended intervention against the natural history of the disease. For patients who are

inoperable and cannot undergo conventional surgical aortic valve replacement (SAVR) surgery, standard therapy comprising medical management with or without balloon aortic valvuloplasty (BAV) offers symptomatic relief only. For patients with symptomatic severe native AS with high surgical risk, conventional SAVR is the current standard of care. TAVI is a viable option to standard therapy for patients who are inoperable, and a less invasive alternative to SAVR for patients with high surgical risk.

Clinical effectiveness and safety

3.1. The Committee noted that TAVI is a minimally invasive procedure that replaces the stenosed aortic valve with a bioprosthetic aortic valve deployed using a catheter, preferably by transfemoral access (through the femoral artery). Other access routes include transapical (through the apex of the heart), transaortic (through the aorta), or transaxillary/subclavian (through the left axillary artery via a small incision beneath the clavicle).

3.2. The Committee noted that there are two main comparators for TAVI: i) standard therapy in patients who are inoperable (Society of Thoracic Surgeons Predicted Risk of Mortality, STS-PROM ≥11%), and ii) SAVR in patients with high surgical risk (STS-PROM 8% to <11%). Safety and clinical effectiveness outcomes were categorised according to the prevailing Valve Academic Research Consortium outcomes.

3.3. Key randomised clinical trials (RCTs) included in the evidence base were PARTNER 1B for patients who were inoperable, and PARTNER 1A and US CoreValve for patients with high surgical risk.

3.4. The Committee agreed that TAVI is likely to have an acceptable safety profile:

- For patients who were inoperable, TAVI via transfemoral access was similar to standard therapy for 30-day all-cause or cardiac mortality, all stroke rates, major bleeding events and permanent pacemaker implantation rates. However, TAVI via transfemoral access was associated with higher major vascular complication rates and higher major stroke rates when compared with standard therapy.
- For patients with high surgical risk, TAVI via any access route was non-inferior to SAVR for 30-day all-cause mortality and stroke rates at one to five years. Furthermore, compared with SAVR, TAVI was associated with higher rates of major vascular complications, moderate or severe aortic regurgitation or paravalvular aortic regurgitation, but shorter hospitalisation and intensive care unit (ICU) stay.

3.5. The Committee acknowledged that the evidence showed TAVI via any access route is likely to be clinically effective in patients who are inoperable. At one to five years of follow-up, TAVI via transfemoral access was associated with lower all-cause or cardiac mortality and rehospitalisation rates when compared with standard therapy. TAVI via transfemoral access was also associated with greater improvements in

disease-related and generic quality of life (QoL) up to one-year follow-up, with a substantially greater proportion of patients with improved functional capacity at one to five years follow-up when compared with standard therapy.

3.6. The Committee acknowledged that for patients with high surgical risk, the evidence showed TAVI via any access route and SAVR had similar all-cause mortality after two years. There was no significant difference in sustained functional capacity improvements and rehospitalisation rates between TAVI and SAVR at up to five years of follow-up. Greater improvements in disease-related and generic QoL were reported for TAVI via any access route at 30 days, but this relative benefit diminished by six months. The Committee agreed that TAVI may not provide substantial additional benefits for all patients with high surgical risk, but a subgroup of patients with unacceptably high surgical risk (STS-PROM ≤11% or with patient characteristics that preclude surgery such as frailty and cognitive function) were likely to have a high unmet clinical need which may be addressed by TAVI, if it was assessed to be a clinically appropriate option by the multidisciplinary heart team.

3.7. The Committee noted that key limitations of the clinical evidence include: the use of early-generation TAVI devices in trials with up to five years of follow-up, incomplete reporting in the studies, and limited longer-term TAVI valve durability data beyond five years, due to its uncertain implications in younger patients.

Cost effectiveness

4.1. The Committee agreed that TAVI via transfemoral access is likely to be cost-effective in patients who are inoperable based on published economic evidence showing consistent cost-effective results. When compared with standard therapy, published incremental cost-effectiveness ratios (ICERs) included a lower bound of SG$11K (AUD$12K) per quality-adjusted life year (QALY) gained and an upper bound SG$51K (¥3.9 million) per QALY gained.

4.2. The Committee noted that ACE developed a local de novo cost-effectiveness model from the healthcare system perspective comparing TAVI via transfemoral access and SAVR in patients with high surgical risk (STS-PROM 8% to <11%), based on evidence from key randomised controlled trials PARTNER 1A and US CoreValve which had up to five years long-term follow-up. The model was simulated over a time horizon of five years in the base case.

4.3. The Committee considered that the ICER was high in patients with high surgical risk at >SG$105,000 per QALY gained. Value-based pricing (VBP) negotiations with manufacturers were needed to lower the ICER, and the cost-effectiveness was likely further improved in a subgroup of patients with unacceptable high surgical risk. The Committee noted that the key drivers of the model were the large cost difference between TAVI and SAVR, and the all-cause mortality rates which converged after two

years. The ICER was also sensitive to the cost of paravalvular aortic regurgitation.

Estimated annual technology cost

5.1. The Committee noted that the annual cost impact to the public healthcare system was estimated to be between SG$1 million to <SG$3 million. This was based on the projection of 12 patients with symptomatic severe native AS who were inoperable in Singapore who would benefit from Government subsidy for TAVI.

5.2. The Committee also noted that the annual cost impact to the public healthcare system was estimated to be SG<$1 million. This was based on the projection of up to 27 patients with symptomatic severe native AS and high surgical risk who would benefit from Government subsidy for TAVI. The actual cost for the subgroup of patients with unacceptable high surgical risk is expected to be minimal.

Organisational feasibility

6.1. The Committee noted that the appropriate accreditation and training, institutional TAVI registries and audit framework are in place in public healthcare institutions (PHIs) to ensure safe and effective TAVI procedures. The Committee agreed that TAVI procedures should be conducted in catheterisation labs or hybrid operating theatres equipped with early in-hospital access to cardiac and vascular surgical support for the emergency treatment of complications and subsequent patient care.

6.2. The Committee also noted that an expansion of regulatory approval for use in groups at lower surgical risk could potentially lead to leakage across patient risk groups.

Additional considerations

7.1. Longer-term valve durability remains limited and may be an increasingly pertinent concern given the growing use of TAVI in younger patients, who may include those with end stage renal failure (ESRF) and those with lower surgical risk. In these patients, it is unclear how often the valve would need to be replaced in their lifetime. The Committee agreed that the rapid innovation cycle of TAVI could potentially limit the generation of longer-term evidence for current TAVI models.

7.2. The Committee further noted that although patients with ESRF could experience futility with TAVI and be at high risk for more frequent TAVI replacements, the use of TAVI in this subgroup could still be justified due to both a lack of ideal alternatives and favourable outcomes with TAVI from some published literature and clinical experience. However, the Committee remained concerned about the high risk for

frequent repeat TAVI procedures in this group due to premature TAVI valve failure before the typical five-year valve durability. To address this, the Committee referenced the reimbursement criteria from Medicare Benefits Schedule (Australia) and agreed it was necessary to strengthen the patient selection process for TAVI subsidy eligibility, by limiting TAVI implant subsidy to patients who have not received a prior SAVR or TAVI implant. This requirement would also help to mitigate the high risk of potential leakage into patients of lower-risk groups.

7.3. The Committee agreed that the multidisciplinary heart team should assess a patient's eligibility for TAVI based on considerations including, but not limited to, clinical eligibility, likely overall benefit from TAVI, and valve durability (particularly in younger patients). Where appropriate, objective tools should be used to assess other surgical risks and other patient characteristics that preclude surgery.

Summary for patients with inoperable and unacceptably high risk

8.1. Based on the evidence presented in November 2020 and March 2021, the Committee recommended subsidy for TAVI in patients with symptomatic severe native AS who are inoperable, or have an unacceptably high risk of mortality from SAVR and significant comorbidities in line with the following criteria:

- ✓ Patient selection should be carried out by a multidisciplinary heart team, which must at minimum include an interventional cardiologist and a cardiac surgeon. The team should determine the surgical mortality risk for each patient based on:
  - An estimated mortality risk of 11% or greater within 30 days of surgery according to the Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) risk assessment; OR
  - Other patient characteristics where these conditions are clinically equivalent to inoperable risk (STS-PROM score ≥11%). These examples could include but are not limited to those listed in the Annex. Where appropriate, objective tools should be used to assess these characteristics.

- ✓ TAVI should be conducted by a multidisciplinary heart team that has met the applicable TAVI training and accreditation standards set by the institution.

- ✓ The TAVI procedure should be performed via transfemoral delivery, unless it is contraindicated or not feasible, in catheterisation labs or hybrid operating theatres equipped with early in-hospital access to cardiac and vascular surgical support for the emergency treatment of complications and subsequent patient care.

- ✓ Properly record details of final surgical risk assessments of all patients who receive TAVI including STS-PROM score, type of TAVI device and clinical outcomes. This is consistent with the standard arrangements in place for clinical governance and audit.

- ✓ TAVI should not be subsidised if the patient has received a prior SAVR or TAVI implant.

Reassessment made by the MOH Medical Technology Advisory Committee (March 2025)

Summary for patients with high surgical risk

9.1. Due to growing unmet clinical need, the Committee reviewed the latest evidence for TAVI in patients with high surgical risk. Based on findings in ACE's evidence update in 2025 for TAVI for patients with AS with high surgical risk, the Committee noted no substantial change to the evidence base and the ICER was lowered based on latest costing data. The Committee determined that TAVI was likely to be non-inferior to SAVR in clinical effectiveness and safety, with an acceptable budget impact.

9.2. In view of its high unmet clinical need, non-inferior safety and clinical effectiveness, and acceptable use of healthcare resources based on prevailing VBP prices of TAVI, the Committee assessed in that it was appropriate to extend subsidy beyond the existing population to include the broader high surgical risk group.

Recommendations of the Health Technology Advisory Council

10.1. At the May 2025 meeting, the Council reviewed the evidence presented in ACE's evidence update of TAVI for patients with severe AS with high surgical risk and considered the assessments made by the MOH Medical Technology Advisory Committee.

10.2. The Council noted that with the clinical evidence base remaining largely unchanged, TAVI may be considered non-inferior to SAVR, and an acceptable use of healthcare resources.

10.3. The Council noted the functional lifespan of TAVI valves ranges from 5 to 10 years and discussed changing trends in TAVI use. With the use of TAVI increasing in younger patients with lower surgical risk, these patients may require multiple replacements over their lifetime. Considering these circumstances, the Council emphasised the importance of developing surgical expertise for technically complex replacement procedures.

10.4. The Council considered that objective assessments by the MDT using both the STS-

PROM score and other validated assessment tools to evaluate conditions deemed clinically equivalent to inoperable or high surgical risk such as frailty or comorbidities that preclude surgery were sufficient and necessary to ensure appropriate treatment selection with TAVI. For frailty assessment, objective measurements such as assessment by physiotherapists and/or validated tools should be used.

10.5. Overall, the Council concluded that based on the high unmet clinical need, non-inferior safety and clinical effectiveness, acceptable use of healthcare resources, and the relevant clinical governance measures in place, the Council recommended including TAVI on the MOH ISL for the treatment of patients with severe AS with high surgical risk.

ANNEX

Other patient characteristics clinically equivalent to the STS-PROM score (≥8%) eligible for subsidy

Patient selection for TAVI should be carried out by a multidisciplinary heart team to determine the surgical mortality risk for each patient based on STS-PROM risk assessment OR other patient characteristics.

Examples of other patient characteristics that are clinically equivalent to inoperable or high risk (STS-PROM score ≥8%) could include but are not limited to:

- Frailty
- Cognitive function
- Porcelain aorta
- Advanced cancer diagnosis but not debilitating
- Prior radiation therapy
- Prior open-heart surgery (e.g. coronary artery bypass graft [CABG])

Where appropriate, objective tools should be used to assess these characteristics. For example, frailty should be assessed via evaluations by the physiotherapist or using validated tools such as the Essential Frailty Toolset.

VERSION HISTORY

Guidance on TAVI
for patients with symptomatic severe native AS

This Version History is provided to track any updates or changes to the guidance following the first publication date. It is not part of the guidance.

1.	**Publication of guidance** Date of Publication	29 Sep 2021
2.	**Amendment to guidance to transit model listings from guidance annex to ISL (formerly known as Med Tech Subsidy List, or MTSL)** Date of Publication	29 Sep 2023
3.	**Updated subsidy criteria for clarity on other patient characteristics** Date of Publication	12 Aug 2024
4.	**Updated subsidy criteria to limit to patients with symptomatic severe native aortic stenosis (AS)** Date of Publication	28 Mar 2025
5.	**Updated subsidy criteria to expand patient population to include patients with high surgical risk (STS-PROM >8% or equivalent)** Date of Publication	27 Mar 2026

Agency for Care Effectiveness - ACE Agency for Care Effectiveness (ACE)

About the Agency

The Agency for Care Effectiveness (ACE) was established by the Ministry of Health (Singapore) to drive better decision-making in healthcare through health technology assessment (HTA), clinical guidance, and education.

As the national HTA agency, ACE conducts evaluations to inform government funding decisions for treatments, diagnostic tests and vaccines, and produces guidance for public hospitals and institutions in Singapore.

This guidance is not, and should not be regarded as, a substitute for professional or medical advice. Please seek the advice of a qualified healthcare professional about any medical condition. The responsibility for making decisions appropriate to the circumstances of the individual patient remains with the healthcare professional.

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