



Australian Government

Medical Services Advisory Committee

Public Summary Document

Application No. 1361.2 – Transcatheter Aortic Valve Implantation via Transfemoral Delivery

Applicant: Edwards Lifesciences Pty Ltd

Date of MSAC consideration: MSAC 66th Meeting, 30-31 March 2016

Context for decision: MSAC makes its advice in accordance with its Terms of Reference, see at www.msac.gov.au

1. Purpose of application and links to other applications

A resubmission requesting Medicare Benefit Schedule (MBS) listing of transcatheter aortic valve implantation (TAVI) for use in patients who are symptomatic with severe aortic stenosis and who are determined to be at high risk for surgical aortic valve replacement or non-operable was received from Edwards Lifesciences Pty Ltd.

2. MSAC's advice to the Minister

After considering the strength of the available evidence in relation to the safety, clinical effectiveness and cost-effectiveness, MSAC supported MBS listing of the TAVI procedure for use in patients who are symptomatic with severe aortic stenosis and who are determined to be at high risk for surgical aortic valve replacement or to be non-operable.

3. Summary of consideration and rationale for MSAC's advice

MSAC recalled that, at its April 2015 meeting consideration of this application, the comparative clinical effectiveness and safety of transcatheter aortic valve implantation (TAVI) had been accepted, including being broadly similar across different TAVI prostheses. However, the cost-effectiveness of TAVI was uncertain and the application was deferred to allow a modified economic model to be represented. A number of the economic concerns raised were addressed in the resubmission provided for the July 2015 meeting. However, at the July 2015 meeting, MSAC again deferred the application to allow the applicant to address remaining concerns with the economic model. Deferral also allowed a stakeholder meeting to address concerns raised by MSAC in relation to the proposed clinical setting.

MSAC noted that, in the lead up to its current reconsideration of the application, an updated economic model had been provided in the resubmission. The revised model had been subjected to a formal assessment with a critique document. The Critique and subsequently

ESC observed that, although changes had been made to the model to address issues raised by MSAC, a number of issues remained outstanding.

MSAC noted the revised base case economic model was restricted to transfemoral delivery only, with an ICER comparing TAVI to medical management for inoperable patients and an ICER comparing TAVI to surgical aortic valve replacement (SAVR) for high-risk surgical patients. In each case, the model was limited to 5 years and informed by relevant 5-year PARTNER trial data. MSAC noted that the resubmission also included two alternative scenario analyses using 24-month data from the CoreValve trial (Reardon et al, 2015) and data from a non-randomised continued access registry. MSAC decided that inconsistencies evident across the alternative scenario models suggested the PARTNER trial data was the most appropriate dataset to be used as the basis for the revised economic model.

MSAC noted that the revised base case ICERs were \$11,708 per QALY gained over medical management for inoperable patients using differential overall survival rates derived from 5-year PARTNER cohort B data (Kapadia et al, 2015) and \$15,541 per QALY gained over SAVR for high-risk surgical patients using differential overall survival rates derived from the 5-year results for the PARTNER Cohort A (Mack et al, 2015). In reviewing the information provided, MSAC confirmed that the revised economic models addressed some, but not all, of the issues raised in July 2015.

MSAC considered the residual outstanding issues with the revised economic model and noted:

- Five-year data from the PARTNER trial had been used in the resubmission to determine outcome benefits in the model. MSAC noted that the base case result in the model comparing TAVI with SAVR in high-risk surgical patients was based on the subgroup of patients from this trial who received their TAVI via the transfemoral route only. These subgroup results were numerically more favourable than the ITT results. MSAC also noted that the numerically different overall survival estimates following TAVI and SAVR were not statistically significantly different in either the ITT analysis or the subgroup analysis.
- The applicant continued to argue against the view held by MSAC that the structure of the model should capture all relevant health states rather than combine observed complications into one health state with the same utility. As a result, in the revised model, two health states (“other complications” and “heart failure follow-up”) were removed and three follow-up health states remained. MSAC expressed concern that the applicant had not adjusted the model as requested. However, as a sensitivity analysis indicated the model had low sensitivity to utility-related issues than to other issues, MSAC decided that this particular issue was not pivotal to its determinations.
- The revised economic model was initially thought to be sensitive to variances in the utility values used, and therefore there was concern that applying a single utility value to a heterogeneous population would not adequately quantify the gain or loss in quality of life. The applicant clarified that the single disutility value had only been applied where patients experienced a major event in the model. The revised sensitivity analyses presented in the ESC report demonstrated that the disutility value was not a key driver of the model. Again, MSAC decided that this particular issue was not pivotal to its determinations.
- MSAC had requested appropriate modelling techniques be applied to mortality and time-dependent complication rates. Different methodological approaches were used in the resubmission and in the Critique, with the latter using overall survival data from the relevant cohorts of the PARTNER trial. Similar ICERs were reported across the two methods for both the inoperable patient cohort (\$11,708/QALY compared with

\$13,692/QALY) and for high-risk surgical patients (\$15,541/QALY compared with \$16,120/QALY). MSAC noted that the resubmission's approach favoured TAVI, but again noting the low sensitivity of the models to this issue than to other issues, MSAC decided that this particular issue was also not pivotal to its determinations.

- The revised economic evaluation relied on the mean ED-5D utility scores at baseline, 30-day, 6-month and 12-month from the relevant cohorts of the PARTNER trial. The utility values accounted for the experience of events that occurred at these time points. Hence, although separate health states were not defined, MSAC considered that the utility values used would have included transvalvular or paravalvular regurgitation.
- In the calculation of hospital costs in the model comparing TAVI with SAVR in high-risk surgical patients, the Critique argued that the inclusion of AR-DRG costs in the revised model is equivalent to double counting and results in overestimation of the real costs. In a subsequent sensitivity analysis, the applicant examined the impact of removing the cost of complications (i.e. cost = \$0) for both TAVI and SAVR (ICER increased from \$15,541/QALY to \$30,914/QALY).
- The Critique argued that the probability of complications in the model comparing TAVI with SAVR in high-risk surgical patients, based on data from Appendix Table 8 of Smith et al, 2011, was 52% for TAVI and 48% for SAVR. The applicant disagreed and maintained the probability of complications should be 41.4% and 47.2% respectively, as presented in the resubmission. MSAC noted that this had been examined in the Critique sensitivity analysis, with the ICER increasing from \$15,541/QALY to \$25,873/QALY.

MSAC noted that the results for inoperable patients, in a sensitivity analysis, were found to be most sensitive to the cost of heart failure follow-up and the cost of index hospitalisation for TAVI. MSAC also noted that sensitivity analyses show the revised model for the high-risk surgical patient cohort is most sensitive to the cost of index hospitalisation of SAVR and the cost of index hospitalisation to TAVI. It is also sensitive to the cost of the TAVI prosthesis and to the cost of complications for SAVR.

MSAC noted that the cost of procedure for SAVR proposed in the resubmission was \$60,884. This included an index hospitalisation cost of \$48,655 based on AR-DRG F04A and a prosthesis cost of \$6,738. The cost of procedure for TAVI was \$64,192 including an index hospitalisation cost of \$24,328 and \$33,348 for the prosthesis. The hospital cost for TAVI was assumed proportional based on TAVI/SAVR length of stay ratio of 1:2 derived from an unpublished data set from Western Australia presented by Yong (2012). MSAC questioned the validity of applying this ratio as it reduces the internal validity of the model as being based directly on the PARTNER trial. Given that all other clinical inputs into the model were derived from the PARTNER trial, the PARTNER-based ratio of 1:1.5 using data from Smith et al (2011) or 1:1.6 using data from Reynolds et al (2012) were therefore suggested as more appropriate. Testing the ratio of 1:1.5 in a sensitivity analysis increased the ICER from \$15,541/QALY to \$44,011/QALY for high-risk surgical patients and from \$11,708 to \$21,450/QALY for inoperable patients. MSAC noted that this approach still favoured TAVI because this calculation assumes that the cost of hospitalisation will be evenly distributed across the length of the hospital stay, whereas it is known that the reductions in hospital stay are typically for the cheaper days (e.g. those which do not incur the costs of the procedure).

MSAC judged that the revised economic model and extensive sensitivity analyses provided by the Critique for the inoperable patient cohort indicate that TAVI is cost effective when compared with medical management. In making this judgement, MSAC was particularly reassured that the more internally valid estimate of \$21,450/QALY was within an acceptable range, and that even with the implausible "worst case" assumption of not reducing the index

hospitalisation cost or the cost of complications from those estimated for SAVR, the estimate of \$49,591/QALY was not a source of concern.

MSAC judged that the greater uncertainty in the revised economic model for TAVI versus SAVR was a source of concern. The more internally valid estimate of \$44,011/QALY increased to \$54,489/QALY when combined in a plausible bivariate sensitivity analysis with the concern about the probability of complications. Most importantly, MSAC did not consider that the claim of an improved overall survival was substantiated in order to justify the incremental cost-effectiveness and incremental cost-utility ratios presented in Steps 3, 4 and 5 of this model, and instead recommended that this aspect of TAVI use be negotiated on a cost-minimisation basis. Further, as much of the incremental cost in the model was driven by the cost of the prosthesis, MSAC advised that negotiation of a reduced benefit for the relevant prostheses when considered for the Prosthesis List would address this concern. MSAC advised that, notwithstanding the CoreValve trial, there was limited evidence of superior safety and clinical effectiveness for TAVI versus SAVR, and as such a cost-minimisation approach should be considered across all prostheses. MSAC advised that the cost-minimisation basis for this negotiation should be that the benefit for any TAVI prosthesis should be no greater than would exceed the current SAVR prosthesis benefit, plus the current AR-DRG cost for the procedure to implant the SAVR prosthesis, minus the application of the 1:1.5 ratio to reduce this AR-DRG cost to implant the TAVI prosthesis. MSAC further advised that this reduced benefit should also apply to the use of TAVI in the other cohort of currently inoperable patients.

MSAC recalled from the July 2015 meeting that the Health Economics Subcommittee of the Prostheses List Advisory Committee had expressed concern about the high cost of the TAVI prosthesis and suggested that there may be room for negotiation. MSAC noted from the analyses in the Critique that for TAVI to be cost-minimised at 12 months, the cost of the TAVI prosthesis would need to decrease by at least \$10,416 from \$33,348 to reflect the basis for cost-minimisation outlined above.

MSAC noted concerns that the size of the inoperable patient population may be underestimated in the revised utilisation and financial estimates provided in the resubmission. However, MSAC anticipated that the uptake would be limited by the number of centres and operators accredited to perform the procedure. The updated financial implications estimated the net cost to the MBS to range from \$2,138,486 in year one to \$2,430,557 in year five. The other healthcare costs, including to the Prostheses List, were estimated to range from \$34,003,951 in year one to \$38,647,802 in year five. MSAC accepted that the total cost would range from \$38,773,151 in year one to \$42,646,318 in year five if the correct MBS rebate of 75% was applied and the estimates included revised TAVI hospitalisation costs and patients of all ages in the calculations.

MSAC acknowledged the value of the information provided at the TAVI stakeholder meeting held in October 2015. MSAC noted that stakeholders had confirmed the importance of the multidisciplinary heart team (MDHT) as a gatekeeper for appropriate patient selection. MSAC agreed with stakeholder recommendations regarding MDHT leadership and core personnel and that the team also be responsible for procedural planning for suitable patients. MSAC also agreed with the recommendation that an assessment of cognitive function and frailty be explicitly included as part of any MBS item descriptor.

MSAC agreed with stakeholders that, in order to retain optimal patient outcomes, it would be necessary to have appropriate accreditation of the TAVI facility, the MDHT involved and the interventional cardiologists and cardio-thoracic surgeons performing TAVI procedures. A

conjoint accreditation arrangement involving the Royal Australasian College of Physicians and Royal Australasian College of Surgeons, and/or their relevant Professional Societies was recommended at the stakeholder meeting, similar to the existing Conjoint Committee for the Recognition of Training in CT Coronary Angiography.

MSAC noted that consultation with the Australian and New Zealand Society of Cardiac and Thoracic Surgeons (ANZSCTS) and the Cardiac Society of Australia and New Zealand (CSANZ) had occurred. Both were supportive of the structure and function of the MDHT, the credentialing of operators and TAVI Centres and mandatory reporting of procedural and patient outcomes.

MSAC supported the establishment of a conjoint committee between the two Societies for accreditation. The joint Position Statement for the Operator and Institutional Requirements for a Transcatheter Aortic Valve Implantation (TAVI) program published in 2014 by ANZSCTS and CSANZ was noted as an important document to inform this process.

MSAC considered two different options for the roles and remuneration of the MDHT. MSAC advised that the option based on existing case conferencing items on the MBS, where the lead/organiser is remunerated higher than other participants, should be adopted. In this option, an interventional cardiologist or cardio-thoracic surgeon would be responsible for leading the TAVI MDHT. This person would be expected to organise and facilitate the meeting of the TAVI MDHT relevant to a potential recipient of a TAVI procedure and would use a new separate MBS item to bill for the TAVI MDHT meeting. This new MBS item would be restricted to be payable only once per patient, would stipulate the identifying characteristics of other members in the TAVI MDHT, and would require that the TAVI MDHT is appropriately accredited. This option would enable the Department of Human Services to identify the individual billing for the TAVI MDHT meeting for each patient and validate their accreditation, to link the TAVI MDHT documentation to a single practitioner.

MSAC noted that consensus between the two Societies was not evident in relation to the need for both a cardio-thoracic surgeon and an interventional cardiologist to be present for a TAVI procedure, nor for a proposal of a 50/50 fee split between both proceduralists. MSAC considered three different options for TAVI procedure remuneration:

- A single item/single proceduralist model, in which one MBS item is claimed by a provider, either an interventional cardiologist or a cardio-thoracic surgeon with schedule fee of \$1909.60
- A single item/dual proceduralist model with one MBS item that could be claimed by two providers, an interventional cardiologist and a cardio-thoracic surgeon with schedule fee of \$954.80
- A multiple item/dual proceduralist model based on existing conjoint surgery items listed on the MBS with a schedule fee in the range totalling \$1909.60 for the entire service.

MSAC noted that the proposed fee for the TAVI procedure was equivalent to SAVR (\$1909.60, based on MBS item 38488), but the estimated procedural time was approximately 60 minutes for TAVI and 120-150 minutes for SAVR. MSAC proposed a reduction in the MBS fee in the order of 25% would be appropriate. MSAC also advised that co-claiming for additional items intrinsic to the procedure such as imaging should not be encouraged. MSAC advised that, irrespective of which accredited provider performs the intervention, it should be a capped fee and that the bundle of services should cost less per patient than SAVR.

MSAC advised that the procedure should be performed by either an interventional cardiologist or a cardio-thoracic surgeon as outlined in the first option above. Credentialing and experience were considered the most important factor in determining who should be present in the operating room. However, if implementation would be facilitated by adopting the third option, MSAC would have no objection, so long as this would retain the Committee's advice to have the MBS fee for the TAVI procedure itself to be about 25% less than that of SAVR.

MSAC advised that the word "available" should be changed to "feasible" in the following introductory sentence of the proposed MBS item descriptor for the TAVI procedure:

TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI) performed by an accredited specialist physician or surgeon in an accredited facility, via transfemoral delivery or another route if transfemoral delivery is contraindicated or not **feasible available**, for the treatment of symptomatic severe aortic stenosis in a suitable patient formally assessed by an accredited heart multidisciplinary team to have an unacceptably high risk for surgical aortic valve replacement.

MSAC noted that the MBS item descriptor for the TAVI procedure would also need to reflect its earlier advice that the selection of a patient for a MBS-funded TAVI procedure must have been determined through an accredited TAVI MDHT, as evidenced for example by the MBS being billed for that earlier service.

MSAC supported a mandatory requirement for registry outcome reporting. Procedure numbers, complications, source of funding (eg MBS or not), and longer term outcomes were all considered essential data to be collected. Data for all TAVI procedures should be collated into a single analysis, irrespective of whether the procedure was performed by an interventional cardiologist or a cardiothoracic surgeon, and results should also be analysed across different funding sources. MSAC recommended that these data and analyses be reviewed at 12-month intervals.

Overall, MSAC supported public funding for TAVI provided that it is cost neutral per patient compared with SAVR. MSAC advised that the proposed MBS fee for the TAVI procedure be decreased by 25%, and that the benefit for the TAVI prosthesis in the Prosthesis List reflect the cost-minimisation basis outlined above.

4. Background

MSAC deferred this application in April 2015 and requested a number of areas of uncertainty in the economic model to be addressed. The resubmission and updated model was then considered by MSAC at its July 2015 meeting and again deferred to allow the applicant to address a number of economic issues and to allow stakeholder consultation in relation to the proposed clinical setting.

The Public Summary Documents are available at <http://www.msac.gov.au/internet/msac/publishing.nsf/Content/1361-public>

5. Economic evaluation

The resubmission presented two stepped economic evaluations, one for the high-risk surgical patient cohort (TAVI-TF vs. SAVR) and one for the inoperable patient cohort (TAVI-TF vs. MM). Table 1 presents a summary of the key changes made in the resubmission.

Table 1: Summary of the key changes and how they are applied in the revised model

Issue	Key changes	How applied in the revised economic evaluation
Structure of the model and health states		
Interventions	Only TAVI-TF is assessed	Two economic evaluations: TAVI-TF vs. SAVR TAVI-TF vs. MM
Duration of the model	Original base case = 10 years Revised base case = 5 years	Stepped economic analysis. Base case: 5 years Sensitivity analysis: 10 years
Health states	Standard therapy follow-up applied to patients who experienced major bleeding, vascular complications, other complications, new pacemaker in the first 30-day post TAVI-TF or SAVR. Standard therapy follow-up applied to patients who experienced major bleeding, other complications, and new pacemaker in the first 30-day post medical management. Post-stroke follow-up is applied to patients who had a stroke. Post heart failure follow-up is applied to patients who had a heart failure while undergoing medical management.	30-day outcomes and 12-month outcomes from PARTNER trial applied in the economic model.
Transition probabilities		
Adverse events	TAVI-TF vs. SAVR: major stroke, vascular complications, major bleeding, pacemaker, subsequent AVR. TAVI-TF vs. MM: major stroke, vascular complications, major bleeding, pacemaker, subsequent AVR.	30-day outcomes and 12-month outcomes from PARTNER trial applied in the economic model.
Mortality rates	Derived from the 5-year PARTNER data for each patient cohort.	5-year outcomes from PARTNER trial data applied to all follow-up health states with no inflation factor.
Costs		
Index hospitalisation	Derived from NHCDC Round 17 for SAVR and applied a ratio of 1:2 for TAVI-TF.	TAVI-TF = \$25,132.49 SAVR = \$48,655.34 Sensitivity analyses
Procedure costs	Proposed fee for TAVI = \$1,909.60	Sensitivity analyses
Cost of TAVI procedure = \$64,191.72	Sensitivity analyses	
Cost of SAVR procedure = \$61,313.33	Sensitivity analyses	
Cost of BAV procedure = \$2,909.73		
Other costs	Costs updated from NHCDC Round 17	
Utility		
Baseline	PARTNER trial data	Applied to each arm
30-day	PARTNER trial data	Applied to each arm
Events	Stroke and heart failure derived from Sullivan et al. using EQ-5D instrument	Sensitivity analyses

The steps of the economic evaluations are summarised in Table 2.

Table 2: Summary of the steps of the economic evaluations

Economic evaluation	High-risk patients vs. SAVR	Inoperable patients vs. medical management
Step 1	Incremental costs with 30-day outcomes	Incremental costs with 30-day outcomes
Step 2	Incremental costs with 12-month outcomes	Incremental costs with 12-month outcomes
Step 3	Incremental cost/LY gained with numerical LY difference over 5 years, ITT population	Incremental cost/LY gained with significant LY difference over 5 years, ITT population

Step 4	Incremental cost/LY gained with larger numerical LY difference over 5 years, TAVI-TF subgroup	Incremental cost/QALY gained with significant LY difference over 5 years, ITT population
Step 5	Incremental cost/QALY gained with numerical difference over 5 years, TAVI-TF subgroup	

ITT = intention-to-treat; LY = life year; QALY = quality-adjusted life year; SAVR = surgical aortic valve replacement; TF-TAVI = transfemoral transcatheter aortic valve implantation

The results of the revised economic evaluations are shown in Table 3.

Table 3: Results of the revised modelled economic evaluation

	TAVI	Comparator	Increment
High-risk surgical patients (TF-TAVI Edwards SAPIEN valve) vs. SAVR: base case in resubmission = Step 5			
Costs	\$90,682	\$86,695	\$3,987
QALYs	2.42	2.16	0.26
Incremental cost/ QALY gained (ICUR)			\$15,541
Inoperable patients (TF-TAVI Edwards SAPIEN valve) vs. medical management: base case in resubmission = Step 4			
Costs	\$95,002	\$86,225	\$8,777
QALYs	1.88	1.13	0.75
Incremental cost/ QALY gained (ICUR)			\$11,708
High-risk surgical patients (TF-TAVI Medtronic CoreValve) vs. SAVR			
Costs	\$85,119	\$89,742	-\$4,623
LYs	1.30	1.19	0.1
Incremental cost/ LY gained (ICER)			Dominated
High-risk surgical patients (TF-TAVI NRCA registry) vs. SAVR			
Costs	\$73,432	\$74,443	-\$1,011
Inoperable patients (TF-TAVI NRCA registry) vs. medical management			
Costs	\$80,172	\$39,894	\$40,278

ICER = incremental cost effectiveness ratio; ICUR = incremental cost utility ratio; LY = life year; NCRA = non-randomised continued access; QALY = quality-adjusted life year; SAVR = surgical aortic valve replacement; TF-TAVI = transfemoral transcatheter aortic valve implantation

The resubmission presented results for key modelling parameters tested in univariate, bivariate and multivariate sensitivity analyses.

In the revised base case for the high-risk surgical patient cohort, the ICER of TAVI-TF vs. SAVR was \$15,541 per QALY. Sensitivity analyses results showed that for the high-risk surgical patient cohort, the revised economic model was most sensitive to the cost of index hospitalisation of SAVR, the cost of index hospitalisation of TAVI-TF, the cost of the TAVI prosthesis and to the cost of complications for SAVR.

In the revised base case for the inoperable patient cohort, the ICER of TAVI-TF vs. MM was \$11,708 per QALY. The results of the sensitivity analyses showed that for the inoperable patient cohort, the revised economic model was most sensitive to the cost of heart failure follow-up and the cost of index hospitalisation for TAVI.

6. Financial/budgetary impacts

The applicant submitted revised utilisation and financial estimates of impact to the MBS and other health services. These financial estimates were based on the disease prevalence study published by Osnabrugge et al (2013), MBS statistics and costs in relation to the revised economic evaluation.

The updated net cost to the MBS ranged from \$2,138,486 to \$2,430,557 per year. The net cost for other parts of the healthcare system was estimated to be \$34,003,951 to \$38,647,802 per year. The combined estimated cost was \$36,142,437 to \$41,078,360 per year.

Table 4: Calculation of forecasted patients used in the financial estimated model with a patient population inclusive of patients < 65 years

	2015	2016	2017	2018	2019
Applicant's submission					
Australian population ≥ 65	3,567,519	3,686,083	3,804,770	3,929,281	4,053,834
Estimate of projected SAVR	0.07%	0.07%	0.07%	0.07%	0.07%
Projected SAVR	2,351	2,429	2,507	2,589	2,671
Critique's calculations					
Estimate of SAVR population < 65	20.7%	19.7%	18.8%	17.8%	16.9%
Calculation	2351 + (2351*0.207)	2429 + (2429*0.197)	2507+ (2507*0.188)	2589 + (2589*0.178)	2671+ (2671*0.169)
Projected SAVR	2,815	2,885	2,954	3,027	3,097

7. Key issues from ESC for MSAC

ESC raised a concern that the \$1909.60 proposed MBS fee is equivalent to SAVR, but that the estimated procedural time is approximately 60 minutes for TAVI and 120-150 minutes for SAVR.

Further, ESC indicated that the item descriptor should specify that a multidisciplinary team is required to perform the procedure in an accredited facility. The composition of that team and which practitioner is able to bill for the item was however regarded as an area of uncertainty.

8. Applicant's comments on MSAC's Public Summary Document

Edwards Lifesciences welcomes the recommendation by MSAC for public funding of transcatheter aortic valve insertion (TAVI) in the defined patient populations. This will improve the quality of life and survival of these patients who otherwise are at high risk of surgery or have no alternative intervention. Of particular note are:

1. the requirement for an appropriately accredited heart team and linking the heart team meeting to each patient
2. the flexibility of MSAC to facilitate implementation allowing either an interventional cardiologist, a cardiothoracic surgeon, or both jointly to perform the procedure
3. the mandatory requirement for a registry with longer-term outcome reporting, with analyses undertaken at 12-monthly intervals.

These requirements will enable funding for access to TAVI with appropriate accountability for this technical and life improving procedure. It is fundamental that the professional

societies jointly develop a patient long term outcome registry that will allow data analysis on an annual basis. The recommendation that the benefit for the TAVI prosthesis in the Prosthesis List reflect cost-equivalence of SAVR based on outcomes at 12 months may not be appropriate when comparing TAVI with medical management in patients who are otherwise inoperable. TAVI is a life extending and quality of life improving procedure, and the incremental cost-effectiveness ratio of less than \$12,000 per QALY gained demonstrates exceptionally good value for money. As such, Edwards Lifesciences believes that a premium over SAVR is warranted for these patients.

9. Further information on MSAC

MSAC Terms of Reference and other information are available on the MSAC Website at: www.msac.gov.au.