Prostheses List – Guidelines for Evaluation of Transcatheter Aortic Valve Implantation (TAVI) or Transcatheter Aortic Valve Replacement (TAVR) devices.

This guide is to be read in conjunction with the Prostheses List - Guide to listing and setting benefits for prostheses.

TAVI are in phase of rapid evolution. Long follow up times are not feasible. However, the clinical importance of valves dictates a minimum of two years for the first in a series. Additionally valve durability becomes increasingly important when used in lower risk groups.

All Therapeutic Products must be included in the Australian Register of Therapeutic Goods (ARTG) before they can be lawfully supplied.

While sponsors may apply for this registration concurrently with an application for listing a product on the Prostheses List, listing a product on the Prostheses List is conditional upon receiving an ARTG certificate.

PARAMETERS

The following must be addressed in a submission for consideration of a TAVI device

1. Structural valve durability

Should conform to that of currently available Tissue valves. Preferably analysed on a competing-risk basis.

2. Paravalvular leakage

Permissible Incidence of aortic regurgitation (AR) post TAVI at any follow up period, including 30 day:

1) Severe AR: 1.5% or less

2) Moderate AR: 5.0% or less

3) Mild AR: 20% or less

4) More than mild AR: 8% or less.

Note: the acceptable incidences will change as further generations of TAV devices reduce the incidence.

Measurement of Severity of AR.

Should be specified as described in:

"Updated standardized endpoint definitions for transcatheter aortic valve implantation. Kappetein *et al*, for the VARC consortium. JACC 60 (15) 1438-54, 2012." Detailed on page 1447, para 2 and table 10.

Reason: Current evidence that less than moderate paravalvular leak does not affect mortality. In using this measurement it is recognised that mortality is a crude parameter of paravalvular leak and that severity is subjective with few studies applying (semi) objective assessment criteria

3. Haemolysis*

4. Endocarditis*

5. Clinical status (NYHA)

Failure to improve or to maintain clinical improvement - NYHA at 12 months

6. Pacemaker requirement

Reason: A Pacemaker not innocuous - risks of the procedure in frail patients, incidence of long term risk. If a patient lives long enough, as increasingly likely in lower risk patients, need for generator replacement. It is noted that Private hospital cost of pacemaker insertion around $18-20K - all of the cost borne by the Health Fund

7. Thromboembolism*

8. Mortality

9. Novelty

For example: a TAV produced using tissue already developed for their Xenograft valve. The modification then, is of the stent and mode of attachment, not the tissue *per se*. However, use of hitherto unproven tissue would be considered separately.

10. Insertion systems

Modification of the insertion system with no change in the valve per se should not need re-evaluation for function nor for benefit change.

11. Stroke*

12. Vascular complications

Reported as per VARC criteria.

13. Duration of follow up required

Duration of follow up data may be influenced by:

The first valve in the series and subsequent modifications, depending on magnitude and significance of the modification.

- For the first valve 2 years
- For modifications one year*

*The acceptable limits for the incidence of these outcomes should conform to that currently applied to other Xenograft valves as described in Guidelines for Evaluation of Artificial Heart Valves.