

The Australian and New Zealand Society of
Cardiac and Thoracic Surgeons

ABN 44 503 186 462



17 February 2015

HTA Health
Canberra ACT

**Re: Submission Based Assessment - 1361 - Transcatheter Aortic Valve Implantation (TAVI)
via Transfemoral or Transapical Delivery.**

Dear Sharon

Thank you for our recent discussion on clarifying the process that the Australian and New Zealand Society of Cardiac and Thoracic Surgeons (ANZSCTS) should follow in responding to requests from the Evaluation Sub-Committee (ESC). We also thank you for the opportunity for the Society as the peak cardiothoracic body in Australia to provide feedback on the consultation protocol on TAVI.

We seek that feedback to the MSAC assessment process ensures that when proposed healthcare interventions are assessed for public funding in Australia; they are patient focused and seek to achieve best value.

The following comments on the TAVI protocol were provided by the Society's representative specialist cardiothoracic surgeons.

Should you have any comments please do not hesitate to write to me or call me on:
02 9328 0605.

Kind regards
Nick Danes
ANZSCTS

TAVI – Consultation Protocol – October 2014

Page 6 – para 3	<p>“Specialist Medical team” should be</p> <p><i>“established Heart Team which includes 2 cardiologists and 2 cardiothoracic surgeons as a minimum (as per FDA guidelines). All patients should be afforded an independent surgical review, and be refused surgery (High risk or inoperable) prior to being considered for TAVI”.</i></p>
Page 6 - para 5	<p>“....unsuitable for AVR but suitable for TAVI.” should be</p> <p><i>“.....unsuitable for AVR but suitable for TAVI regardless of risk score assessment.”</i></p>
Page 12 - para 3	<p><u>Delivery of the proposed intervention</u></p> <p>TAVI should only be undertaken with a multidisciplinary ‘heart team’. The multidisciplinary team would include the following members:</p> <ul style="list-style-type: none"> • Interventional cardiologist; • Cardiothoracic surgeon; • Anaesthetist; and • TAVI nurse case manager/co-ordinator. <p><i>Add: It is a minimum requirement these proceduralists (x1 Interventionalist, x1 cardiac surgeon) to be involved with each TAVI implant – regardless of mode of delivery. Funding should be limited to cases where this minimum has been met.</i></p>
Page 14 point 8	<p>We question why a minimum of 2 proctored cases (TF and TA) is used here. For Interventionalist (p12) and Cardiac surgeon (p13) the minimum proctored cases are 10.</p> <p><i>We would recommend a minimum of 10 proctored (supervised) cases remain as the minimum standard.</i></p>
Table 7	<p>We agree with independent MBS item for transcatheter valve implant. We also agree with it being consistent with standard AVR (38488 item number).</p> <p>The descriptor should mandate minimum proceduralists as x1 interventionalist and x1 cardiac surgeon for funding approval.</p>
Page 19 Q3	Yes. And should be minimum requirement for CMBS funding.
Page 19 Q4	One CMBS for “Transcatheter TAVI” will be enough. Access via other routes would be associated with other CMBS codes already available (i.e.. 38488, 38418, etc.). This will also allow improved tracking of device use.

Opinion

ANZSCTS strongly advises the minimum requirement for Heart Team Assessment and the minimum requirement for Procedural Team include a cardiac surgeon, as per current FDA guidelines. This will ensure adequate patient assessment and ensure appropriateness of device use. Secondly, there is considerable overlap between TransFemoral and other (TransApical or Trans Aortic) approaches. Maintenance of skillsets and procedural team efficiencies would benefit from this involvement and consistency of team members. In addition, procedural complications may require rapid surgical involvement which would be unlikely available, or compromised, if surgical team members are not readily available. Finally, the requirement for Interventional Cardiology involvement will also ensure both Cardiology and Surgical Teams are involved and these devices are only implanted in a cohesive and collaborative environment, ensuring best outcomes and appropriateness of decision making towards TAVI and sAVR in this high risk patient group.