

**TRANSCATHETER AORTIC VALVE
IMPLANTATION**

**RULES FOR THE ACCREDITATION OF
TAVI PRACTITIONERS**

CARDIAC ACCREDITATION SERVICES LIMITED

(Version 1, 1 November, 2017)

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1 Purpose

These Rules establish the processes and criteria for the "**Accreditation**", "**Reaccreditation**", "**Review**" and "**Deaccreditation**" of TAVI Practitioners (Cardiothoracic Surgeon and/or Interventional Cardiologist) to perform transcatheter aortic valve implantation (**TAVI**) as an item on the Medicare Benefits Schedule (**MBS**).

2 Background

- 2.1 Pursuant to subsection 3C(1) of the *Health Insurance Act 1973* (Cth), an authorised delegate for the Minister for Health has made the *Health Insurance (Section 3C General Medical Services - Transcatheter Aortic Valve Implantation) Determination 2017*(Cth) (**TAVI Determination**), which provides for the listing of TAVI and associated services as items on the MBS, commencing on 1 November 2017.
- 2.2 The item descriptors for TAVI and associated services, in Schedule 1 of the TAVI Determination, are available at www.mbsonline.gov.au. When terms that are defined in the TAVI Determination are used in these Rules, they have the same meaning as in the TAVI Determination.
- 2.3 The Commonwealth Department of Health (**Department**) has authorised the Australian & New Zealand Society of Cardiac & Thoracic Surgeons (**ANZSCTS**) and the Cardiac Society of Australia and New Zealand (**CSANZ**) to develop the processes and criteria for the accreditation of TAVI Practitioners, and carry out the accreditation of those TAVI Practitioners.
- 2.4 To serve as the vehicle for this accreditation activity, ANZSCTS and CSANZ have incorporated Cardiac Accreditation Services Limited, ACN 622 113 044 (**Cardiac Accreditation Services**), a company limited by guarantee, whose sole two members are ANZSCTS and CSANZ.
- 2.5 The TAVI Determination formally recognises Cardiac Accreditation Services' accreditation role by defining a TAVI Practitioner as "either a cardiothoracic surgeon or interventional cardiologist who is accredited by Cardiac Accreditation Services Limited."
- 2.6 Cardiac Accreditation Services has established, and Cardiac Accreditation Services' Board has delegated its authority to:
- (a) the "**TAVI Accreditation Committee**" to make decisions on applications for Accreditations and Reaccreditations and, in some circumstances, to conduct Reviews of a TAVI Practitioner's Accreditation that may lead to that TAVI Practitioner's Deaccreditation ; and
 - (b) the "**TAVI Appeals Committee**", to consider appeals from decisions of the TAVI Accreditation Committee to Accredite, Reaccredit or Deaccredit TAVI Practitioners.
- 2.7 Cardiac Accreditation Services has appointed officers to perform the secretariat function required to support the operation of the TAVI Accreditation Committee and the TAVI Appeals Committee.

2.8 If a TAVI Practitioner has been Accredited under these Rules to perform TAVI they will only be able to claim the TAVI item number if the other applicable requirements are fulfilled, including:

- (a) any requirements of the TAVI Determination, including that TAVI be performed in a hospital, as defined by subsection 121-5(5) of the *Private Health Insurance Act 2007*, that is "clinically accepted" as being a suitable hospital in which the service described in Item 38495 may be performed (**TAVI Hospital**); and

Note: The Explanatory Statement to the TAVI Determination, and the Explanatory Notes to the relevant MBS items which appear on MBS Online, refer to the minimum standards of what will be "clinically accepted". These minimum standards are reproduced in **Attachment A** to these Rules.

- (b) the TAVI Practitioner has been accredited to perform the TAVI procedure at the TAVI Hospital(s) indicated at the time of application for accreditation and the Hospital meets criteria described in Joint Position Statement to be considered "clinically suitable." That is, the fact that it is a TAVI Hospital is not sufficient and the TAVI Practitioner must advise the TAVI Accreditation Committee in writing any changes to the TAVI Hospital(s) where the procedure will be performed.

3 **TAVI Accreditation Committee**

3.1 The membership of the TAVI Accreditation Committee is:

- (a) 3 members of ANZSCTS, nominated by ANZSCTS; and
- (b) 3 members of CSANZ, nominated by CSANZ.

3.2 At any time, at least one member of the 3 nominated by each Society to the TAVI Accreditation Committee must not be a TAVI Practitioner.

3.3 The position of Chair of the TAVI Accreditation Committee will be held for two years, on an alternating basis between ANZSCTS and CSANZ. For the avoidance of doubt, this provision does not determine the affiliation of the first Chair.

3.4 The quorum for the TAVI Accreditation Committee is 4 members, including 1 member who is not a TAVI Practitioner.

3.5 The term for membership of the TAVI Accreditation Committee is 3 years, and a person may serve a maximum of 2 consecutive terms.

3.6 Proceedings of the TAVI Accreditation Committee are to be confidential.

4 **Applications for, and Decisions on, Accreditation and Reaccreditation**

4.1 All applications for Accreditation and Reaccreditation must be submitted to the TAVI Accreditation Committee using the application form prescribed by the TAVI Accreditation Committee, if any (see www.tavi.org.au), and must be accompanied by the fee to apply for Accreditation as determined by the TAVI Accreditation Committee.

- 4.2 If the TAVI Accreditation Committee Accredits a TAVI Practitioner for a period of less than 3 years, the TAVI Accreditation Committee will provide a pro rata refund to the TAVI Practitioner.
- 4.3 A TAVI Practitioner must lodge an application for Reaccreditation, using the application form prescribed by the TAVI Accreditation Committee, if any (see www.tavi.org.au), no sooner than 6 months, and no later than 3 months, before the date of expiry of their current Accreditation.
- 4.4 The TAVI Accreditation Committee will consider applications for Accreditation or Reaccreditation quarterly. The date for submission each quarter will be posted on www.tavi.org.au.
- 4.5 In response to a complying application, the TAVI Accreditation Committee must decide whether to:
- (a) Accredit a TAVI Practitioner, taking into account the criteria in section 5; or
 - (b) Reaccredit a TAVI Practitioner, taking into account the criteria in section 6.
- Note:** In most cases, if a person meets the criteria for Accreditation or Reaccreditation, the TAVI Accreditation Committee will Accredit or Reaccredit that person as a TAVI Practitioner. Equally, in most cases, if a person fails to meet the criteria for Accreditation or Reaccreditation, the TAVI Accreditation Committee will not Accredit or Reaccredit that person as a TAVI Practitioner. In some cases, there may be good reason for the TAVI Accreditation Committee to use its discretion deviate from those practices. For example, if a TAVI Practitioner's failure to meet the mortality rate criteria was adequately explained by their patient cohort being in significantly poorer condition than the average TAVI patient, that failure would not justify a decision not to Reaccredit that practitioner.
- 4.6 Within 7 days of deciding whether to Accredit or Reaccredit a TAVI Practitioner, the TAVI Accreditation Committee must provide written notice of its decision to the TAVI Practitioner and to the Department of Human Services.
- 4.7 Where the TAVI Accreditation Committee decides not to Accredit or Reaccredit a TAVI Practitioner, in addition to the notice of its decision to the TAVI Practitioner, it must provide:
- (a) reasons for its decision;
 - (b) advice that the TAVI Practitioner may appeal the decision within 28 days of receiving the notice by completing the prescribed form for an appeal; and
 - (c) a copy of these Rules.
- 4.8 A TAVI Practitioner must obtain Reaccreditation within 3 years of being Accredited or Reaccredited.
- 4.9 Notwithstanding paragraph 4.88, in order to stagger the work of the TAVI Accreditation Committee for Reaccreditation, when the TAVI Accreditation Committee accredits a TAVI Practitioner, especially during the first year of the TAVI Accreditation Committee's operation, the TAVI Accreditation Committee may stipulate a period for the Reaccreditation of anywhere between 1 year and 3 years.

5 **Criteria for Accreditation**

- 5.1 TAVI Practitioners must have completed FRACP Cardiology or FRACS Cardiothoracic Surgery.
- 5.2 TAVI Practitioners may apply to the TAVI Accreditation Committee under one of three categories. The requirements for each category are listed below.
- 5.3 Category 1, titled "**Established TAVI Operator (Interventional Cardiologist or Cardiothoracic Surgeon)**", will have the following criteria:
- (a) >60 TAVIs performed in Australia and/or New Zealand in the past 2 years as primary or secondary operator, as evidenced by a completed log book (with UR numbers, procedure dates, access site, major complications, hospital outcome); and
 - (b) either of the following:
 - (i) \geq 400 career percutaneous coronary interventions (**PCI**); or
 - (ii) \geq 40 career surgical aortic valve replacements.
- 5.4 Category 2A, titled "**New TAVI Operator – Interventional Cardiologist**" will have the following criteria:
- (a) >30 TAVIs (as primary or secondary operator) and >10 balloon aortic valvuloplasties as primary operator in a recognised TAVI training program; and
 - (b) a minimum of 10 proctored TAVI cases in Australia or New Zealand with appropriate certification of completion of training; and
 - (c) >250 career percutaneous coronary interventions.
- as evidenced by a completed log book (with UR numbers, procedure dates, access site, major complications, hospital outcome)
- 5.5 Category 2B, titled "**New TAVI Operators – Cardiothoracic surgeons**" will have the following criteria:
- (a) >30 TAVIs (as primary or secondary operator) in a recognised TAVI training program; and
 - (b) a minimum of 10 proctored TAVI cases in Australia or New Zealand with appropriate certification of completion of training; and
 - (c) >20 career surgical aortic valve replacements.
- as evidenced by a completed log book (with UR numbers, procedure dates, access site, major complications, hospital outcome)
- 5.6 Overseas trained operators will be required to have the log book signed by their supervisor, and a letter certifying satisfactory completion of the training by the overseas institution's program co-ordinator.

6 **Criteria for Reaccreditation**

- 6.1 The TAVI Accreditation Committee will Reaccredit the TAVI Practitioner if the practitioner meets the following criteria in respect of each year of the previous Accreditation or Reaccreditation period:
- (a) subject to paragraph 6.2, >30 cases of TAVI per year as primary or secondary operator in an Accredited TAVI Institution;
 - (b) 30-day mortality rate <5%;
 - (c) One-year mortality rate <15%;
 - (d) 30-day CVA/TIA rate <8%;
 - (e) 30-day major vascular complication rate <5%;
 - (f) >90% submission of completed data to the TAVI National Registry (including one-year outcomes).
- 6.2 Notwithstanding paragraph 6.1(a), where a TAVI Practitioner has not been practicing for some or all of a year, the TAVI Accreditation Committee may decide to reduce the required minimum number of TAVI cases pro rata.

7 **Review of Accreditation**

- 7.1 The TAVI Accreditation Committee may conduct a Review of a TAVI Practitioner's Accreditation at any time, either on its own initiative, or where there is a request for a Review from:
- (a) an authorised representative of a TAVI Hospital;
 - (b) CSANZ or ANZSCTS; or
 - (c) an authorised representative of a government or statutory agency with regulatory responsibilities relevant to TAVI Accreditation or Reaccreditation.
 - (d) National TAVI Registry
- 7.2 The TAVI Accreditation Committee may decide to conduct a Review where it has reason to suspect that a TAVI Practitioner meets the "**Deaccreditation Criteria**":
- (a) the TAVI Practitioner has been incorrectly Accredited; or
 - (b) in any one year of Accreditation, the TAVI Practitioner has failed to meet the Reaccreditation criteria.
 - (c) Identified as an outlier to accepted outcomes reporting by the National TAVI Registry
- 7.3 On receipt of a request, the TAVI Accreditation Committee may investigate matters relevant to the Deaccreditation Criteria, including by making inquiries of the requester, the Individual Operator, or anyone else.
- 7.4 When the TAVI Accreditation Committee receives a request for a Review, it must:

- (a) decide to conduct the Review, where there is a reasonable suspicion that the TAVI Practitioner who is the subject of the request meets the Deaccreditation Criteria; or
 - (b) decline to conduct the Review, where the request does not raise that suspicion.
- 7.5 Within 7 days of deciding to conduct a Review, either in response to a request or on its own initiative, the TAVI Accreditation Committee must provide the TAVI Practitioner with:
- (a) written notice of the TAVI Accreditation Committee's decision to conduct a Review:
 - (i) stating the reasons for the Review;
 - (ii) advice that the TAVI Practitioner may lodge a written submission to the Review, completing any form for that purpose prescribed by the TAVI Accreditation Committee, within 28 days of receiving the notice; and
 - (b) a copy of these Rules.
- 7.6 No oral representations to the TAVI Accreditation Committee, or any member of the TAVI Accreditation Committee, are permitted. The only submission from the TAVI Practitioner that will be considered is a submission in writing.
- 7.7 After considering any submission by the TAVI Practitioner and making any further inquiries that it considers appropriate, the TAVI Accreditation Committee must decide whether or not to Deaccredit the TAVI Practitioner.
- 7.8 The TAVI Accreditation Committee must provide the TAVI Practitioner with written notice of its decision within 7 days of making the decision.

8 **TAVI Appeals Committee**

- 8.1 The standing membership of the TAVI Appeals Committee is:
- (a) a lawyer who has been a registered practitioner in Australia for a minimum of 7 years, who will be the Chair of the TAVI Appeals Committee;
 - (b) 2 members of ANZSCTS, neither of who is the President of ANZSCTS, jointly nominated by ANZSCTS and CSANZ; and
 - (c) 2 members of CSANZ, neither of who is the President of CSANZ, jointly nominated by ANZSCTS and CSANZ.

None of the members of the TAVI Appeals Committee will be members of the current TAVI Accreditation Committee.

- 8.2 When considering an appeal, the TAVI Appeals Committee will convene with only 3 members:
- (a) the lawyer member, who is the Chair of the TAVI Appeals Committee;
 - (b) an ANZSCTS member; and

(c) a CSANZ member.

8.3 The term for membership of the TAVI Appeals Committee is 3 years, and a person may serve a maximum of 2 consecutive terms.

8.4 Proceedings of the TAVI Appeals Committee are to be confidential.

9 **Appeal Process**

9.1 Within 30 days of receiving a notice that the TAVI Accreditation Committee has decided not to Accredite or Reaccredit a TAVI Practitioner, or has decided to Deaccredit them, that TAVI Practitioner may apply to the TAVI Appeals Committee to have the merits of that decision reviewed by the TAVI Appeals Committee.

9.2 An application for an appeal must be in the form prescribed by the TAVI Accreditation Committee, if any (see www.tavi.org.au), and must:

- (a) identify the aspects of the TAVI Accreditation Committee's decision that are contested;
- (b) give reasons for contesting those aspects that are contested;
- (c) provide any additional information which the TAVI Practitioner would like the TAVI Appeals Committee to consider.

9.3 An application for an appeal must be accompanied by a fee of \$500 to cover administrative costs. If the TAVI Appeals Committee upholds the appeal, the application fee will be refunded.

9.4 No oral representations to the TAVI Appeals Committee, or any member of the TAVI Appeals Committee, are permitted. The only submission from the TAVI Practitioner that will be considered is a written submission in the form prescribed by the TAVI Accreditation Committee, if any.

9.5 When the TAVI Appeals Committee receives an application for appeal, it must decide whether to:

- (a) reject the appeal; or
- (b) uphold one or more elements of the appeal and substitute its decision for the decision of the TAVI Accreditation Committee.

Attachment A - Criteria for Clinically Acceptable TAVI Hospital

1. Requirements For Clinically Acceptable TAVI Hospital

The following are the minimum requirements that should be met in order for a facility to be a 'clinically acceptable' TAVI Hospital.

A declaration by the most senior executive officer of the TAVI Hospital attesting to the TAVI Hospital's infrastructure and clinical activity must be submitted by the TAVI Practitioner at the time of application.

- (a) Interventional Cardiology annual volume:
 - (i) >1000 diagnostic cardiac procedures; AND
 - (ii) >300 percutaneous coronary interventions AND
- (b) Cardiothoracic Surgery annual volume/staffing:
 - (i) >30 surgical aortic valve replacements; AND
 - (ii) >150 major cardiac surgery procedures; AND
 - (iii) >30 arterial endovascular procedures
 - (iv) Minimum of two on-site cardiac surgeons skilled in aortic valve surgery, with staff equipment and theatre space to provide urgent surgical backup (as per requirements for surgical support documented in Joint Position Statement)
 - (v) On-site vascular surgical staff and expertise to manage major arterial access/complications
- (c) Interventional facilities/infrastructure:
 - (i) Cardiac catheterisation laboratory/hybrid operating theatre with fixed cineangiography and haemodynamic monitoring system
 - (ii) Sufficient space to accommodate anaesthesia, echocardiography, and cardiopulmonary bypass equipment
 - (iii) Transthoracic and transoesophageal echocardiography
 - (iv) Vascular ultrasound imaging/expertise in image interpretation
 - (v) Appropriate equipment to deal with complete heart block, large vessel rupture, pericardial tamponade, haemodynamic collapse
 - (vi) Post procedure high dependency unit (ICU, CCU) experienced in managing cardiac surgical patients
 - (vii) Anticipated annual TAVI volume of >50cases/year (or >100 per two years)

- (d) A formal Heart Team that meets regularly to review candidates for TAVI. The team must include at least:
 - (i) An Interventional Cardiologist
 - (ii) A Cardiothoracic Surgeon
 - (iii) A specialist not otherwise directly participating in the TAVI (e.g. Clinical Cardiologist, Geriatrician, ICU specialist, Anaesthetist)
 - (iv) A Nurse Co-ordinator
- (e) Infrastructure and personnel for maintenance of a TAVI database, and data submission to the TAVI National Registry.

2. Ongoing Requirements for a Clinically Acceptable TAVI Hospital

Each year a 'clinically acceptable' TAVI hospital should meet the following requirements:

- (i) An annual TAVI volume of >50cases
- (ii) 30-day mortality <5%
- (iii) One-year mortality of <15%
- (iv) 30-day CVA/TIA rate <8%
- (v) 30-day major vascular complication rate <5%
- (vi) >90% submission of completed data to the TAVI National Registry including one-year outcomes