MBS LISTING FOR TRANSCATHETER AORTIC VALVE IMPLANTATION (TAVI)

Last updated: 26/10/2017

Effective from 1 November 2017

From 1 November 2017, Medicare rebates will be available for transcatheter aortic valve implantation (TAVI) and associated services for use in patients who are symptomatic with severe aortic stenosis, and who are deemed to be at high risk for surgical aortic valve replacement or who would otherwise be inoperable.

MBS Item Descriptors

<table>
<thead>
<tr>
<th>MBS Item</th>
<th>Item Descriptor</th>
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<tbody>
<tr>
<td>6080</td>
<td>Coordination of a TAVI Case Conference by a TAVI Practitioner where the TAVI Case Conference has a duration of 10 minutes or more. (Not payable more than once per patient in a five year period.)</td>
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<tr>
<td>6081</td>
<td>Attendance at a TAVI Case Conference by a specialist or consultant physician who does not also perform the service described in item 6080 for the same case conference where the TAVI Case Conference has a duration of 10 minutes or more. (Not payable more than twice per patient in a five year period.)</td>
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<tr>
<td>38495</td>
<td>TAVI, for the treatment of symptomatic severe aortic stenosis, performed via transfemoral delivery, unless transfemoral delivery is contraindicated or not feasible, in a TAVI Hospital on a TAVI Patient by a TAVI Practitioner – includes all intraoperative diagnostic imaging that the TAVI Practitioner performs upon the TAVI Patient. (Anaes.) (Assist.) (Not payable more than once per patient in a five year period.)</td>
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What does the new procedure involve?

MBS item 38495 is for a TAVI service for the treatment of symptomatic severe aortic stenosis in a suitable patient formally assessed to have an unacceptably high risk for surgical aortic valve replacement.

In order to attract a Medicare Benefit, the patient’s eligibility for the TAVI service is to be approved through a TAVI Case Conference, and the service has to be performed by an interventional cardiologist or a cardiothoracic surgeon who has been accredited by the Cardiac Accreditation Services Limited and performed at a hospital that is considered clinically accepted as being suitable.
What are the patient eligibility requirements?

Only patients who have been formally assessed as having an unacceptably high risk for surgical aortic valve replacement will be eligible for TAVI. Practitioners are required to assess the patient suitability through a TAVI-specific case conference.

Patients who have been assessed as suitable for surgical aortic valve replacement will not be eligible for TAVI.

What is a TAVI Case Conference?

A TAVI Case Conference is a process undertaken by a number of medical practitioners to assess and make recommendations regarding a patient’s suitability to receive TAVI.

The TAVI Case Conference is to include an assessment of:

- the patient’s risk and technical suitability for a surgical aortic valve replacement; and
- the patient’s cognitive function and frailty.

A TAVI Case Conference must comprise a team of three or more participants including:

- one cardiothoracic surgeon;
- one interventional cardiologist; and
- one specialist or consultant physician who does not perform the TAVI procedure for the patient being assessed.

Either the cardiothoracic surgeon, or the interventional cardiologist must also be an accredited TAVI Practitioner.

More than three participants can be involved in a TAVI Case Conference. The composition of a TAVI Case Conference beyond the above minimum requirements is a matter for the coordinating practitioner based on the individual circumstances of the patient. However, the patient is only eligible to receive a Medicare rebate for one coordinating participant, and two attending participants.

Medicare rebates will only be payable for one TAVI Case Conference, per patient, in a five year period.

While a TAVI Case Conference must occur to assess a patient’s suitability, it is not mandatory for a patient to be billed this service in order for a benefit to be paid under the TAVI procedure item 38495.

What items can be billed for the TAVI Case Conference?

Item 6080 provides for the coordination of the TAVI Case Conference and is only payable once per patient in a five year period.

The TAVI Coordinator is responsible for:

- ensuring that the patient is aware of the purpose and nature of the patient’s TAVI Case Conference and has consented to their TAVI Case Conference;
- recording the day the conference was held, and the times the conference started and ended;
- recording the names of the participants of the conference;
- provision of expertise to inform the recommendation resulting from the case conference;
- recording minutes of the TAVI Case Conference including the recommendation resulting from the conference;
- ensuring that the patient is aware of the recommendation.
Where the TAVI Coordinator is not the patients treating practitioner, they should liaise with the treating practitioner to ensure the patient has been properly informed.

**Item 6081** provides for **attendance** at a TAVI case conference by a specialist or consultant physician who attended but did not coordinate the conference. This item is only payable twice per patient in a five year period.

An attending participant is responsible for:

- retaining a record of the day the conference was held, and the times the conference started and ended;
- retaining a record of the names of the participants;
- provision of expertise to inform the recommendation resulting from the case conference;
- retaining a record of the recommendation resulting from the conference.

**Who can perform a TAVI procedure?**

A TAVI Practitioner can be either a cardiothoracic surgeon or interventional cardiologist who is accredited by Cardiac Accreditation Services Limited.

**What is the role and function of the Cardiac Accreditation Services Limited?**

Cardiac Accreditation Services Limited, is responsible for developing the processes and criteria for the accreditation of TAVI Practitioners; the setting of minimum standards for TAVI Hospitals; and accrediting TAVI Practitioners.

Cardiac Accreditation Services Limited is comprised of representatives from the Australian & New Zealand Society of Cardiac & Thoracic Surgeons (ANZSCTS) and the Cardiac Society of Australia and New Zealand (CSANZ).

**What are the accreditation requirements for TAVI Practitioners?**

Cardiac Accreditation Services Limited set the minimum standards and volume requirements that need to be met for accreditation as a TAVI Practitioner.

Cardiac Accreditation Services Limited notifies the Department of Human Services (DHS) of accredited TAVI Practitioners and the facilities in which they operate from. It is important to note that it is a TAVI Practitioner’s responsibility to notify Cardiac Accreditation Services of every TAVI Hospital they are operating in, over the life of their accreditation.

Detailed accreditation requirements are set out in the *Transcatheter Aortic Valve Implantation – Rules for the Accreditation of TAVI Practitioners*, issued by Cardiac Services Accreditation Limited.

This document, and further information on TAVI accreditation and appeals processes are available on the [TAVI accreditation](#) website, or by directly contacting Cardiac Accreditation Services Limited through its [website](#).

**Where can a TAVI procedure take place?**

A TAVI Hospital is 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 at which TAVI procedures may be performed.
The Transcatheter Aortic Valve Implantation - Rules for the Accreditation of TAVI Practitioners, issued by Cardiac Accreditation Services Limited, provides guidance regarding clinically acceptable TAVI facilities.

What TAVI medical devices are listed on the Prostheses List?

The purpose of the Prostheses List is to ensure that privately insured Australians have access to clinically effective prostheses that meet their health care needs.

The Prostheses List enables surgeons to have access to and choose the optimal prostheses for patients covered by private health insurance. It lists surgically implanted prostheses, human tissue items and other medical devices that private health insurers must pay benefits for when:

- they are provided to a patient with appropriate health insurance cover;
- they are provided as part of hospital treatment or hospital substitute treatment; and
- there is a Medicare benefit payable for the professional service associated with the provision of the prosthesis.

Three TAVI devices will be available on the Prostheses List from 1 November 2017 to coincide with the availability of MBS items for TAVI.

The Prostheses List minimum benefit will be $22,932. This benefit is based on the Medical Services Advisory Committee (MSAC) determined maximum cost-effective price for devices used in TAVI.

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<th>Sponsor</th>
<th>Product</th>
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<tr>
<td>Medtronic Australasia Pty Ltd</td>
<td>Medtronic CoreValve™ Evolut™ R transcatheter aortic valve</td>
</tr>
<tr>
<td>Edwards Lifesciences Pty Ltd</td>
<td>Edwards SAPIEN 3 Transcatheter Heart Valve</td>
</tr>
<tr>
<td>St Jude Medical Australia Pty Ltd</td>
<td>Portico transcatheter aortic valve</td>
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Review and monitoring of TAVI Services

The utilisation of these new TAVI items, including service volumes, provider and location details, will be monitored closely post implementation to ensure appropriate use of these items. A review will be conducted by the Department of Health on service utilisation at around six months post listing of these items.

In addition the Medical Services Advisory Committee (MSAC) has implemented a formal reporting process to monitor the utilisation of MBS items that were positively supported by the MSAC, following at least 24 months since their initial MBS listing. The intent of this process is to (1) improve the MSAC application process by creating a feedback loop to report to MSAC the real world impacts of its positively supported applications and (2) monitor utilisation to ensure the new items or item amendments are being used as intended.

Key Definitions

**TAVI Patient**: A patient who, as a result of a TAVI Case Conference, has been assessed as having an unacceptably high risk for surgical aortic valve replacement and is recommended as being suitable to receive the service described in item 38495.

**TAVI Practitioner**: A cardiothoracic surgeon or interventional cardiologist who is accredited by the Cardiac Accreditation Services Limited.
TAVI Hospital: 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 Case Conference: A process by which:

(a) there is a team of 3 or more participants, where:
   (i) the first participant is a cardiothoracic surgeon; and
   (ii) the second participant is an interventional cardiologist; and
   (iii) the third participant is a specialist or consultant physician who does not perform a service described in Item 38495 for the patient being assessed; and
   (iv) either the first or the second participant is also a TAVI Practitioner; and

(b) the team assesses a patient’s risk and technical suitability to receive the service described in Item 38495, taking into account matters such as:
   (i) the patient’s risk and technical suitability for a surgical aortic valve replacement; and
   (ii) the patient’s cognitive function and frailty; and

(c) the result of the assessment is that the team makes a recommendation about whether or not the patient is suitable to receive the service described in Item 38495; and

(d) the particulars of the assessment and recommendation are recorded in writing.

TAVI Case Conference Coordinator: undertakes all of the following activities in relation to a TAVI Case Conference:

(a) ensuring that the patient is aware of the purpose and nature of the patient’s TAVI Case Conference and has consented to their TAVI Case Conference;

(b) recording the day the conference was held, and the times the conference started and ended;

(c) recording the names of the participants of the conference;

(d) provision of expertise to inform the recommendation resulting from the case conference;

(e) recording minutes of the TAVI Case Conference including the recommendation resulting from the conference;

(f) ensuring that the patient is aware of the recommendation.

TAVI Case Conference Attendee: undertakes all of the following activities in relation to a TAVI Case Conference:
(a) retaining a record of the day the conference was held, and the times the conference started and ended;
(b) retaining a record of the names of the participants;
(c) provision of expertise to inform the recommendation resulting from the case conference;
(d) retaining a record of the recommendation resulting from the conference.

Further information

For further information on TAVI accreditation requirements, please visit the Cardiac Accreditation Services Limited website or contact the Cardiac Accreditation Services Limited.