



# New and amended MBS items for Transcatheter Aortic Valve Implantation (TAVI)

**Date of change:** 1 March 2022

**Legislation:** Health Insurance (Section 3C General Medical Services – Transcatheter Aortic Valve Implantation) Amendment (Limit to Intermediate and High Risk Surgical Patients) Determination 2021

**New item:** **38514**

**Amended item:** **38495**

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## What are the changes?

One new Medicare Benefits Schedule (MBS) item (38514) will be introduced on 1 March 2022 for TAVI for patients with symptomatic severe aortic stenosis at intermediate risk for open surgical aortic replacement, device agnostic.

One MBS item (38495) will be amended for TAVI for patients with symptomatic severe aortic stenosis at high risk for open surgical aortic replacement, device agnostic.

Item 38495 (high risk) and item 38514 (intermediate risk) will provide for the separate populations who qualify for these services. There will continue to be two attendance items including item 6080 (for the coordination of a TAVI suitability case conference) and item 6081 (for a participant in the suitability case conference) to determine patient suitability.

This change is relevant to interventional cardiologists and cardiothoracic surgeons with relevant training in TAVI implant insertion. Providers of the procedures associated with items 38495 and 38514 must also be accredited with the TAVI Accreditation Committee.

The final recommendation to list this service by the Medical Services Advisory Committee (MSAC) occurred in April 2021. Further details about MSAC applications can be found under [MSAC Applications](#) on the MSAC website ([www.msac.gov.au](http://www.msac.gov.au)).

## Patient impacts

These changes reflect modern clinical practice and will enable patients to receive a Medicare rebate for the new intermediate risk service (38514) when clinically appropriate.

This new procedural item will assist patients who experience the debilitating effects of aortic stenosis by providing a less invasive, surgical treatment option for those who are at intermediate risk for open surgery. Currently, when open



surgical aortic valve replacement is considered too high risk or is contraindicated for high risk patients, they have the option to undergo a TAVI procedure. High risk patients (38495) will continue to have access to TAVI procedures, however with this change intermediate surgical risk patients will also gain access to this well established treatment option as an alternative to open surgical aortic replacement or repair.

It is expected that patient access to the new TAVI intermediate risk population service will complement the already established high risk population MBS service, helping improve physical and emotional functioning, and reducing related morbidity and hospitalisations.

## Restrictions or requirements

An MBS service for the implantation of a TAVI device (items 38495 and 38514) is only claimable every five years, which includes a five year restriction on the accompanying attendance items (6080 and 6082). It is also important to note that item 38495 cannot be claimed within five years of item 38514 and vice versa.

The services associated with items 38495 and 38514 can only be claimed in relation to a patient where the procedure has been provided by TAVI accredited practitioner in a TAVI accredited hospital. This accreditation can only be provided by the TAVI Accreditation Committee.

## New item 38514 – Transcatheter Aortic Valve Implantation (TAVI) for the treatment of symptomatic severe aortic stenosis in a TAVI patient that is at intermediate risk for open surgical aortic replacement

**Overview:** This item introduces a new service for the transcatheter implantation of a TAVI device (device agnostic with ARTG listing), for patients who are at an intermediate risk for open surgical aortic valve replacement.

### Service/Descriptor:

TAVI, for the treatment of symptomatic severe aortic stenosis, performed via transfemoral delivery, unless transfemoral delivery is contraindicated or not feasible, if:

- (a) the TAVI patient is at intermediate risk for surgery; and
- (b) the service:
  - (i) is performed by a TAVI practitioner in a TAVI Hospital; and
  - (ii) includes all intraoperative diagnostic imaging that the TAVI Practitioner performs upon the TAVI Patient;

not being a service which has been rendered within 5 years of a service to which this item or 38495 applies

(H) (Anaes.) (Assist.)

### Other requirements:

A TAVI suitability case conference has determined and documented that the patient is suitable for the service.

The service is performed by an interventional cardiologist or cardiothoracic surgeon who has been accredited by the TAVI Accreditation Committee.



The service is performed at a hospital that is accredited by the TAVI Accreditation Committee as a suitable hospital for the service.

**Billing requirement:**

Item 38514 is not claimable within 5 years of items 38495 or 38514; and

The service associated with item 38514 includes all intraoperative imaging.

**MBS fee:** \$1,490.25

**Benefit:** 75% only

**Proposed Private Health Insurance Classifications:**

**Proposed Clinical Category:** Heart and Vascular System

**Proposed Procedure Type:** Type A – Advanced Surgical

**Amended item 38495 – Transcatheter Aortic Valve Implantation (TAVI) for the treatment of symptomatic severe aortic stenosis in a TAVI patient that is at high risk for open surgical aortic replacement**

**Overview:** This amended item continues as the service for the transcatheter implantation of a TAVI device (device agnostic with ARTG listing), for patients who are at high risk for open surgical aortic valve replacement.

**Service/Descriptor:**

TAVI, for the treatment of symptomatic severe aortic stenosis, performed via transfemoral delivery, unless transfemoral delivery is contraindicated or not feasible, if:

(a) the TAVI patient is at high risk for surgery; and

(b) the service:

(i) is performed by a TAVI Practitioner in a TAVI Hospital; and

(ii) includes all intraoperative diagnostic imaging that the TAVI Practitioner performs upon the TAVI Patient;

not being a service which has been rendered within 5 years of a service to which this item or 38514 applies

(H) (Anaes.) (Assist.)

**Other requirements:**

A TAVI suitability case conference has determined and documented that the patient is suitable for the service.

The service is performed by an interventional cardiologist or cardiothoracic surgeon who has been accredited by the TAVI Accreditation Committee.

The service is performed at a hospital that is accredited by the TAVI Accreditation Committee as a suitable hospital for the service.



### **Billing requirement:**

Item 38495 is not claimable within 5 years of items 38514 or 38495; and

The service associated with item 38495 continues to include all intraoperative imaging.

**MBS fee:** \$1,490.25

**Benefit:** 75% only

### **Proposed Private Health Insurance Classifications:**

**Proposed Clinical Category:** Heart and Vascular System

**Proposed Procedure Type:** Type A – Advanced Surgical

## **What does the new procedure involve?**

MBS item 38514 is for a TAVI service for the treatment of symptomatic severe aortic stenosis in a suitable patient who has been formally assessed to have an intermediate risk for open surgical aortic valve replacement. MBS item 38495 continues to provide for a TAVI service for symptomatic severe aortic stenosis in a suitable patient formally assessed to have a high risk for open surgical aortic valve replacement.

In order to attract a Medicare benefit, the patient's eligibility for the TAVI services 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 TAVI Accreditation Committee and performed at a hospital accredited by the TAVI Accreditation Committee as a suitable hospital for the service.

## **What are the eligibility requirements?**

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

## **What is a TAVI suitability case conference?**

A TAVI suitability case conference is a process undertaken by a number of specialist (or consultant physician) medical practitioners to assess and make recommendations regarding a patient's suitability to receive TAVI using the available ARTG listed TAVI implants.

The TAVI suitability 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 suitability 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 who performs the procedure associated with items 38514 or 38495 must also be an accredited TAVI Practitioner.

More than three participants can be involved in a TAVI suitability case conference. The composition of a TAVI suitability 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, whether associated with item 38514 or 38495.

While a TAVI suitability 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 items 38514 and 38495.

## What items can be billed for the TAVI Case Conference?

**Item 6080** provides for the **coordination of the TAVI** suitability case conference and is only payable once per patient in a five-year period.

The TAVI suitability 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 the details, including the particulars of the assessments of the patient during the TAVI case conference and the recommendations resulting from the conference;
- ensuring that the patient is aware of the recommendation.

Where the TAVI coordinator is not the patient's 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 suitability 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:

- provision of expertise to inform the assessment of the patient and the recommendations resulting from the case conference

## Who can perform a TAVI procedure?

A TAVI Practitioner can be either a cardiothoracic surgeon or interventional cardiologist who is accredited by the TAVI Accreditation Committee.



## What is the role and function of the TAVI Accreditation Committee?

The TAVI Accreditation Committee is responsible for developing the processes and criteria for the accreditation of TAVI Practitioners; the setting of minimum standards and accreditation of TAVI Hospitals; and accrediting TAVI Practitioners.

The TAVI Accreditation Committee (under the incorporated entity 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?

The TAVI Accreditation Committee sets the minimum standards and volume requirements that need to be met for accreditation as a TAVI Practitioner.

TAVI Accreditation Committee notifies Services Australia 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 the TAVI Accreditation Committee of every TAVI Hospital they are operating in, over the life of their accreditation.

Detailed accreditation requirements and further information is available by contacting the TAVI Accreditation Committee (Cardiac Accreditation Services Limited) at [tavi@tavi.org.au](mailto:tavi@tavi.org.au).

## 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.

## TAVI medical devices and private health insurance coverage.

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

## Review and monitoring of TAVI Services

The utilisation of the new and amended 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 12-24 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

<b>TAVI Patient:</b>	A patient who, as a result of a TAVI suitability Case Conference, has been assessed as having an unacceptably high risk or intermediate risk for surgical aortic valve replacement and is recommended as being suitable to receive the services described in items 38495 or 38514.
<b>TAVI Practitioner:</b>	A cardiothoracic surgeon or interventional cardiologist who is accredited by the TAVI Accreditation Committee.
<b>TAVI Hospital:</b>	A hospital, as defined by subsection 121-5(5) of the <i>Private Health Insurance Act 2007</i> , that is clinically accepted as being a suitable hospital in which the service described in item 38495 or 38514 may be performed.
<b>TAVI Suitability Case Conference:</b>	<p>A process by which:</p> <p>(a) there is a team of 3 or more participants, where:</p> <ol style="list-style-type: none"> <li>(i) the first participant is a cardiothoracic surgeon; and</li> <li>(ii) the second participant is an interventional cardiologist; and</li> <li>(iii) the third participant is a specialist or consultant physician who does not perform a service described in item 38495 or 38514 for the patient being assessed; and</li> <li>(iv) either the first or the second participant is also a TAVI Practitioner; and</li> </ol> <p>(b) the team assesses a patient’s risk and technical suitability to receive the service described in item’s 38495 or 38514, taking into account matters such as:</p> <ol style="list-style-type: none"> <li>(i) the patient’s risk and technical suitability for a surgical mitral valve replacement; and</li> <li>(ii) the patient’s cognitive function and frailty; and</li> </ol> <p>(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 or 38514; and</p> <p>(d) the particulars of the assessment and recommendation are recorded in writing.</p>
<b>TAVI Suitability Case Conference Coordinator</b>	Undertakes all of the following activities in relation to a TAVI Suitability Case Conference:



	<p>(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;</p> <p>(b) recording the day the conference was held, and the times the conference started and ended;</p> <p>(c) recording the names of the participants of the conference;</p> <p>(d) provision of expertise to inform the recommendation resulting from the case conference;</p> <p>(e) recording the details of the TAVI Case Conference including the particulars of the assessments of the patient and the recommendation resulting from the conference;</p> <p>(f) ensuring that the patient is aware of the recommendation.</p>
<b>TAVI Suitability Case Conference Attendee</b>	<p>Undertakes all of the following activities in relation to a TAVI Suitability Case Conference:</p> <p>(a) provide expertise in the assessment of the patient</p> <p>(b) provision of expertise to inform the recommendation resulting from the case conference.</p>

## Further information

For further information on TAVI accreditation requirements, please visit the TAVI Accreditation Committee website or email: [tavi@tavi.org.au](mailto:tavi@tavi.org.au).

To view previous item descriptors and deleted items, visit MBS Online at [www.mbsonline.gov.au](http://www.mbsonline.gov.au), navigate to 'Downloads' and then select the relevant time period at the bottom of the page. The old items can then be viewed by downloading the MBS files published in the month before implementation of the changes

*Please note that the information provided is a general guide only. It is ultimately the responsibility of treating practitioners to use their professional judgment to determine the most clinically appropriate services to provide, and then to ensure that any services billed to Medicare fully meet the eligibility requirements outlined in the legislation.*

*This sheet is current as of the Last updated date shown above, and does not account for MBS changes since that date.*