



New MBS items for Transcatheter Mitral Valve repair (TMVr - MitraClip™)

Date of change: 01 July 2021

Legislation: [Health Insurance \(Section 3C General Medical Services—Transcatheter Mitral Valve Repair\) Determination 2021 \(legislation.gov.au\)](#)

New items: 38461 38463 6082 6084

What are the changes?

- Four new MBS items will be introduced 1 July 2021 for transcatheter mitral valve repair (TMVr) using the MitraClip™ valve implant.
- Two procedural items including item 38461 (degenerative) and item 38463 (functional) will provide for the separate populations who qualify for these services, and there will be two attendance items including item 6082 (for the coordination of a TMVr suitability case conference) and item 6084 (for a participant in the suitability case conference).
- This change is relevant to interventional cardiologists and cardiothoracic surgeons with relevant training in transcatheter mitral valve repair using the MitraClip™ implant system. Providers of the procedures associated with items 38461 and 38463 must also be accredited with the TMVr Accreditation Committee.
- These new procedural services will be available to patients with moderate-severe mitral valve regurgitation that is either degenerative (primary) or functional (secondary) and who are at an unacceptably high risk for surgical mitral valve replacement.
- The listing of this service was recommended by the Medical Services Advisory Committee (MSAC) in April 2020. Further details about MSAC applications can be found under [MSAC Applications](#) on the MSAC website (www.msac.gov.au).

Patient impacts

- Patients will receive Medicare rebates for new services that are clinically appropriate and reflect modern clinical practice.
- Importantly, these new procedural items will provide a surgical treatment option for patients (who are high risk for open surgery) and experience the debilitating effects of heart failure, secondary to mitral valve regurgitation. Currently, when open surgical mitral valve replacement is considered too high risk or is absolutely contraindicated,



a patient may only be managed with the use of optimal medical therapy, which may be sub-optimal and severely effect their activities of daily living.

- It is expected that patient access to the TMVr procedure for two defined populations, will help improve physical and emotional functioning, and reduce related morbidity and hospitalisations.

Restrictions or requirements

- An MBS service for the implantation of a MitraClip™ device (items 38461 and 38463) is only claimable every 5 years, which includes a 5 year restriction on the accompanying attendance items (6082 and 6084).
- The services associated with items 38461 and 38463 can only be claimed in relation to patient where the procedure has been provided by TMVr accredited practitioner in a TMVr accredited hospital. This accreditation can only be provided by the TMVr Accreditation Committee.

New item 38461 – Transcatheter Mitral Valve Repair (TMVr) using the Mitraclip™ implant for moderate to severe, or severe, symptomatic degenerative (primary) mitral valve regurgitation (grade 3+ or 4+)

Overview: This item introduces a new service for the permanent coaptation of the mitral valve leaflets using one or more Mitraclips for patients with moderate to severe, or severe, symptomatic degenerative (primary) mitral valve regurgitation (grade 3+ or 4+), who are at an unacceptably high risk for surgical mitral valve replacement.

Service/Descriptor:

TMVr, by transvenous or transeptal techniques, for permanent coaptation of mitral valve leaflets using one or more Mitraclips, including intra-operative diagnostic imaging, if:

(a) the patient has each of the following risk factors:

- (i) moderate to severe, or severe, symptomatic degenerative (primary) mitral valve regurgitation (grade 3+ or 4+);
 - (ii) left ventricular ejection fraction of 20% or more;
 - (iii) symptoms of mild, moderate or severe chronic heart failure (New York Heart Association class II, III or IV);
- and

(b) as a result of a TMVr suitability case conference, the patient has been:

- (i) assessed as having an unacceptably high risk for surgical mitral valve replacement; and
- (ii) recommended as being suitable for the service; and

(c) the service is performed:

- (i) by a cardiothoracic surgeon, or an interventional cardiologist, accredited by the TMVr Accreditation Committee to perform the service; and
- (ii) via transfemoral venous delivery, unless transfemoral venous delivery is contraindicated or not feasible; and



(iii) in a hospital that is accredited by the TMVr Accreditation Committee as a suitable hospital for the service;
and

(d) a service to which this item, or item 38463, applies has not been provided to the patient in the previous 5 years
(H) (Anaes.) (Assist.)

Other requirements:

A TMVr 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 TMVr Accreditation Committee.

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

Billing requirement:

Item 38461 is not claimable within 5 years of items 38461 or 38463; and

The service associated with item 38461 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

New item 38463 – Transcatheter Mitral Valve Repair (TMVr) using the Mitraclip™ implant for moderate to severe, or severe, symptomatic functional (secondary) mitral valve regurgitation (grade 3+ or 4+).

Overview: This item introduces a new service for the permanent coaptation of the mitral valve leaflets using one or more Mitraclips for patients with moderate to severe, or severe, symptomatic functional (secondary) mitral valve regurgitation (grade 3+ or 4+), who are at an unacceptably high risk for surgical mitral valve replacement.

Service/Descriptor:

TMVr, by transvenous or transeptal techniques, for permanent coaptation of mitral valve leaflets using one or more Mitraclips, including intra-operative diagnostic imaging, if:

(a) the patient has each of the following risk factors:



- (i) moderate to severe, or severe, symptomatic functional (secondary) mitral valve regurgitation (grade 3+ or 4+);
 - (ii) left ventricular ejection fraction of 20% to 50%;
 - (iii) left ventricular end systolic diameter of not more than 70mm;
 - (iv) symptoms of mild, moderate or severe chronic heart failure (New York Heart Association class II, III or IV) that persist despite maximally tolerated guideline directed medical therapy; and
- (b) as a result of a TMVr suitability case conference, the patient has been:
- (i) assessed as having an unacceptably high risk for surgical mitral valve replacement; and
 - (ii) recommended as being suitable for the service; and
- (c) the service is performed:
- (i) by a cardiothoracic surgeon, or an interventional cardiologist, accredited by the TMVr Accreditation Committee to perform the service; and
 - (ii) via transfemoral venous delivery, unless transfemoral venous delivery is contraindicated or not feasible; and
 - (iii) in a hospital that is accredited by the TMVr Accreditation Committee as a suitable hospital for the service; and
- (d) a service to which this item, or item 38461, applies has not been provided to the patient in the previous 5 years
- (H) (Anaes.) (Assist.)

Other requirements:

A TMVr 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 TMVr Accreditation Committee.

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

Billing requirement:

Item 38463 is not claimable within 5 years of items 38461 or 38463; and

The service associated with item 38463 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



New item 6082 – TMVr suitability case conference (Coordinator) attendance

Overview: This item introduces a new service for a TMVr suitability case conference coordinator who is accredited by the TMVr Accreditation Committee for the purposes of determining a patient's suitability for a TMVr service.

Service/Descriptor:

Attendance at a TMVr suitability case conference, by a cardiothoracic surgeon or an interventional cardiologist, to coordinate the conference, if:

- (a) the attendance lasts at least 10 minutes; and
- (b) the surgeon or cardiologist is accredited by the TMVr Accreditation Committee to perform the service

Applicable once each 5 years

Other requirements:

The coordinating surgeon or cardiologist is accredited by the TMVr Accreditation Committee; and

Must last at least 10 mins.

Billing requirement:

Item 6082 is only claimable each 5 years.

MBS fee: \$52.95

Benefit: 75% and 85 % only

Proposed Private Health Insurance Classifications:

Proposed Clinical Category: Heart and Vascular System

Proposed Procedure Type: Type C (note this is an attendance item)

New item 6084 – TMVr suitability case conference (Attendee – other than to coordinate)

Overview: This item introduces a new service for an attendee at a TMVr suitability case conference who is a specialist or consultant physician, for the purposes of determining a patient's suitability for a TMVr service.

Service/Descriptor:

Attendance at a TMVr suitability case conference, by a specialist or consultant physician, other than to coordinate the conference, if the attendance lasts at least 10 minutes

Applicable once each 5 years



Other requirements:

The attendance must last at least 10 mins.

Billing requirement:

Item 6084 is only claimable each 5 years.

MBS fee: \$39.50

Benefit: 75% and 85 % only

Proposed Private Health Insurance Classifications:

Proposed Clinical Category: Heart and Vascular System

Proposed Procedure Type: Type C (note this is an attendance item)

What does the new procedure involve?

MBS item 38461 is for a TMVr service for the treatment of symptomatic degenerative (primary) moderate to severe or severe mitral valve regurgitation in a suitable patient formally assessed to have an unacceptably high risk for surgical mitral valve replacement. MBS item 38463 is for a TMVr service for the treatment of symptomatic functional (secondary) moderate to severe or severe mitral valve regurgitation in a suitable patient formally assessed to have an unacceptably high risk for surgical mitral valve replacement.

In order to attract a Medicare Benefit, the patient's eligibility for the TMVr services is to be approved through a TMVr case conference, and the service has to be performed by an interventional cardiologist or a cardiothoracic surgeon who has been accredited by the TMVr Accreditation Committee and performed at a hospital accredited by the TMVr 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 for surgical mitral valve replacement will be eligible for TMVr using the MitraClip™ implant. Practitioners are required to assess the patient suitability through a TMVr-specific case conference.

Patients who have been assessed as suitable for surgical mitral valve replacement will not be eligible for TMVr using the MitraClip™ implant.

What is a TMVr suitability case conference?

A TMVr 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 TMVR using the MitraClip™ implant.



The TMVr 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 TMVr 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 TMVr procedure for the patient being assessed.

Either the cardiothoracic surgeon or the interventional cardiologist who performs the procedure associated with items 38461 or 38463 must also be an accredited TMVr Practitioner.

More than three participants can be involved in a TMVr suitability case conference. The composition of a TMVr 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 TMVr case conference, per patient, in a five year period, whether associated with item 38461 or 38463.

While a TMVr 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 TMVr procedure items 38461 and 38463.

What items can be billed for the TMVr Case Conference?

Item 6082 provides for the **coordination of the TMVr** suitability case conference and is only payable once per patient in a five-year period.

The TMVr suitability Coordinator is responsible for:

- ensuring that the patient is aware of the purpose and nature of the patient's TMVr case conference and has consented to their TMVr 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 TMVr case conference and the recommendations resulting from the conference;
- ensuring that the patient is aware of the recommendation.



Where the TMVr coordinator is not the patient's treating practitioner, they should liaise with the treating practitioner to ensure the patient has been properly informed.

Item 6084 provides for **attendance** at a TMVr 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 TMVr procedure?

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

What is the role and function of the TMVr Accreditation Committee?

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

The TMVr 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 TMVr Practitioners?

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

TMVr Accreditation Committee notifies Services Australia of accredited TMVr Practitioners and the facilities in which they operate from. It is important to note that it is a TMVr Practitioner's responsibility to notify the TMVr Accreditation Committee of every TMVr Hospital they are operating in, over the life of their accreditation.

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

Where can a TMVr procedure take place?

A TMVr 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 TMVr procedures may be performed.



What TMVr 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.

Two TMVr devices will be available on the Prostheses List from 1 July 2021 to coincide with the availability of MBS items for TMVr:

Sponsor	Product
Abbott Medical Australia Pty Ltd	Mitraclip mitral valve clip
Abbott Medical Australia Pty Ltd	Mitraclip G4 mitral valve clip

Review and monitoring of TMVr Services

The utilisation of these new TMVr 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

TMVr Patient: A patient who, as a result of a TMVr 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 services described in items 38461 or 38463.



TMVr Practitioner: A cardiothoracic surgeon or interventional cardiologist who is accredited by the TMVr Accreditation Committee.

TMVr 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 38461 or 38463 may be performed.

TMVr Suitability 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 38461 or 38463 for the patient being assessed; and
 - (iv) either the first or the second participant is also a TMVr Practitioner; and
- (b) the team assesses a patient's risk and technical suitability to receive the service described in item's 38461 or 38463, taking into account matters such as:
 - (i) the patient's risk and technical suitability for a surgical mitral 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 38461 or 38463; and
- (d) the particulars of the assessment and recommendation are recorded in writing.

TMVr Suitability Case Conference

Coordinator: Undertakes all of the following activities in relation to a TMVr Suitability Case Conference:

- (a) ensuring that the patient is aware of the purpose and nature of the patient's TMVr Case Conference and has consented to their TMVr 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 the details of the TMVr Case Conference including the particulars of the assessments of the patient and the recommendation resulting from the conference;
- (f) ensuring that the patient is aware of the recommendation.

TMVr Suitability Case Conference

Attendee: Undertakes all of the following activities in relation to a TMVr Suitability Case Conference:

- (a) provide expertise in the assessment of the patient
- (b) provision of expertise to inform the recommendation resulting from the case conference.

Further information

For further information on TMVr accreditation requirements, please visit the TMVr Accreditation Committee website or email: tavi@tavi.org.au.

To view previous item descriptors and deleted items, visit MBS Online at 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.