Australian Government
Department of Health and Aged Care

MSAC recommendations:

Amendment (item 38461) – for transcatheter mitral valve repair (TMVr) by transvenous or transeptal techniques to be device agnostic for the treatment of degenerative mitral regurgitation (DMR)

Date of change: 1 November 2024

Amended item: 38461

Revised structure

- From 1 November 2024, Medicare Benefits Schedule (MBS) item 38461 will be amended, to move from a device specific descriptor (MitraClip™) to a device agnostic descriptor. This change will permit use of any Australian Register of Therapeutic Goods (ARTG) listed devices in addition to the MitraClip™ device for the treatment of degenerative mitral regurgitation (DMR).
- In future, devices that are listed on the ARTG for use in patients with:

  (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

  will be able to be used in association with this service.
- This change is relevant to interventional cardiologists and cardiothoracic surgeons with relevant training in transcatheter mitral valve repair. Providers of the procedures associated with item 38461 must be accredited with the Transcatheter Mitral Valve Therapies (TMVT) Accreditation Committee.
- The amendment was supported by the Medical Services Advisory Committee (MSAC) at its 4 April 2024 meeting and was approved for funding on the MBS in the 2023-24 Budget. Further details about MSAC applications can be found under MSAC Applications on the MSAC website.

Patient impacts

- Clinicians and patients will now have additional treatment options for moderate to severe, or severe, symptomatic degenerative (primary) mitral valve regurgitation (grade 3+ or 4+). This change will allow an additional device to be accessed for transcatheter mitral valve repair and also allow future devices that gain ARTG listing to be accessed.
- It is expected that patient access to addiitonal devices, will continue to help improve physical and emotional functioning, and reduce related morbidity and hospitalisations.

Restrictions or requirements

- An MBS benefit for the implantation of a mitral valve tissue approximation device (item 38461) is only claimable every 5 years, which includes a 5 year restriction on the accompanying attendance items (6082 and 6084).
- Services under item 38461 may only be provided by providers, and at hospitals, who are accredited with the TMVT Accreditation Committee.
- Providers are responsible for ensuring Medicare services claimed using their provider number meet all legislative requirements. All Medicare claiming is subject to compliance checks and providers may be required to submit evidence about the services they bill. More information about the Department's compliance program can be found on its website at Medicare compliance.

Amended item 38461 – The reduction of mitral regurgitation through tissue approximation using transvenous/transeptal techniques

Item: TMVr, by transvenous or transeptal techniques, for permanent coaptation of mitral valve leaflets using one or more tissue approximation implants.

Overview: This item is being amended to permit claiming for any device (agnostic) that is ARTG listed to treat moderate to severe, or severe, symptomatic degenerative (primary) mitral valve regurgitation (grade 3+ or 4+).

Descriptor

TMVr, by transvenous or transeptal techniques, for permanent coaptation of mitral valve leaflets using one or more ~~MitraClip™~~ tissue approximation implants, 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.

Billing requirement: Claimable once every 5 years when the service is provided by practitioners accredited by the Transcatheter Mitral Valve Therapies (TMVT) Accreditation Committee.

MBS fee: $1,631.65.

Benefit: 75% $1,223.75

Private Health Insurance clinical category: Heart and Vascular System

Private Health Insurance procedure type: Type A – Advanced Surgical

Amended item descriptors (to take effect 1 November 2024)

Category 3 – Therapeutic Procedures
Group T8 – Surgical Operations
Subgroup 6 – Cardio Thoracic
38461 TMVr, by transvenous or transeptal techniques, for permanent coaptation of mitral valve leaflets using one or more tissue approximation implants, 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:

Category 3 – Therapeutic Procedures

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.

- **Private Health Insurance Classification:**
- **Clinical category:** Heart and vascular system
- **Procedure type:** Type A – Advanced Surgical

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.