

## EXPLANATORY STATEMENT

### *Health Insurance Act 1973*

#### *Health Insurance (Section 3C General Medical Services Table – Transcatheter Mitral Valve Repair) Determination 2021*

Subsection 3C(1) of the *Health Insurance Act 1973* (the Act) provides that the Minister may, by legislative instrument, determine that a health service not specified in an item in the general medical services table (the Table) shall, in specified circumstances and for specified statutory provisions, be treated as if it were specified in the Table.

The Table is set out in the regulations made under subsection 4(1) of the Act. The most recent version of the regulations is the *Health Insurance (General Medical Services Table) Regulations (No. 2) 2020*. This regulation will be remade from 1 July 2021 and will be titled the *Health Insurance (General Medical Services Table) Regulations 2021*.

#### **Purpose**

The *Health Insurance (Section 3C General Medical Services – Transcatheter Mitral Valve Repair) Determination 2021* (the Determination) lists four new items (6082, 6084, 38461 and 38463) to enable symptomatic patients who have moderate-severe or severe degenerative (primary) mitral valve regurgitation, or symptomatic patients who have moderate-severe or severe functional (secondary) mitral valve regurgitation to undergo a transcatheter mitral valve repair (TMVr) with the MitraClip system.

Mitral valve regurgitation (MR) is a condition which occurs when the heart's mitral valve does not close tightly and blood flows backward in the heart. To compensate for the MR, the heart muscle must increase its contraction, putting extra burden on the left ventricle of the heart and lungs. Eventually, this burden can cause other problems, such as stroke, sudden death, irregular heartbeat, increasing damage to the heart muscle or the inability to maintain adequate systemic circulation of blood.

The prevalence of MR increases with age. Currently, surgical management is a well-established pathway for patients in Australia, but typically many patients do not undergo open surgery because of their high-risk status which can include advanced age or other comorbidities.

In April 2020, the Medical Services Advisory Committee (MSAC) supported public funding for TMVr with MitraClip for patients with mitral regurgitation who are unable to or are at high-risk for open heart surgery (MSAC assessment 1192.3).

The Determination will list four new items to provide a less invasive approach through transcatheter repair with the MitraClip system. The Determination lists two new items for a patient to attend a TMVr suitability case conference, for a cardiothoracic surgeon or an interventional cardiologist (for a service under new item 6082), or for a specialist or consultant physician (for a service under new item 6084) to assess the patient's suitability to undergo a transcatheter repair with the MitraClip system. These services can only be provided once every five years.

The Determination also lists two items for TMVr by permanent coaptation of the heart's mitral valve by using the Mitraclip system (items 38461 and 38463). A service under these items is to be provided if the patient has been assessed by a TMVr suitability case conference (under items 6082 or 6084) as having an unacceptably high risk of surgical mitral valve replacement, and has been recommended for this service. A service under items 38461 and 38463 can only be provided by a cardiothoracic surgeon or an interventional cardiologist, who is accredited by Cardiac Accreditation Services Limited, and can only be provided in a clinically suitable TMVr hospital. These services can only be provided once every five years.

The Government agreed to this MSAC decision in the 2021-22 Budget as part of the *Guaranteeing Medicare — changes to the Medicare Benefits Schedule* measure.

### **Consultation**

MSAC reviews new or existing medical services or technology, and the circumstances under which public funding should be supported through listing on the Medicare Benefits Schedule (MBS). This includes the listing of new items, or amendments to existing items on the MBS.

As part of the MSAC process, consultation was undertaken with key stakeholders, including the Cardiac Society of Australia and New Zealand (CSANZ), Australian and New Zealand Society of Cardiac and Thoracic Surgeons, independent clinical experts and providers, and consumer health representatives.

Details of the Determination are set out in the [Attachment](#).

The Determination commences on 1 July 2021.

The Determination is a legislative instrument for the purposes of the *Legislation Act 2003*.

Authority: Subsection 3C(1) of the  
*Health Insurance Act 1973*

**Details of the *Health Insurance (Section 3C General Medical Services – Transcatheter Mitral Valve Repair) Determination 2021*.**

Section 1 – Name

Section 1 provides for the Determination to be referred to as the *Health Insurance (Section 3C General Medical Services – Transcatheter Mitral Valve Repair) Determination 2021*.

Section 2 – Commencement

Section 2 provides that the Determination commences on 1 July 2021.

Section 3 – Authority

Section 3 provides that the Determination is made under subsection 3C(1) of the *Health Insurance Act 1973*.

Section 4 – Definitions

Section 4 defines terms used in the Determination.

Section 5 – Treatment of transcatheter mitral valve services

Section 5 provides the treatment of the transcatheter mitral valve services provided under items 6082, 6084, 38472 and 38474.

Subsections 5(1) to 5(4) provides that a clinically relevant service provided in accordance with the Determination shall be treated, for relevant provisions of the *Health Insurance Act 1973* and *National Health Act 1953*, and regulations made under those Acts, as if it were both a professional service and a medical service and as if there were an item specified in the medical general services table for the service.

Items 6082 and 6084 are to be treated as if they were located in Part 2 of the general medical services table (which deals with attendances), and items 38461 and 38463 are to be treated as if they were located in subgroup 6 of Group T8 of Part 5 of the general medical services table (which deals with cardio-thoracic surgical operations).

Subsection 5(5) specifies the health services and prescribes the associated fees for items 6082, 6084, 38461 and 38463.

## Statement of Compatibility with Human Rights

*Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011*

*Health Insurance (Section 3C General Medical Services – Transcatheter Mitral Valve Repair) Determination 2021*

This instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

### Overview of the Determination

The *Health Insurance (Section 3C General Medical Services – Transcatheter Mitral Valve Repair) Determination 2021* (the Determination) lists four new items (6082, 6084, 38461 and 38463) to enable symptomatic patients who have moderate-severe or severe degenerative (primary) mitral valve regurgitation, or symptomatic patients who have moderate-severe or severe functional (secondary) mitral valve regurgitation to undergo a transcatheter mitral valve repair (TMVr) with the MitraClip system.

Mitral valve regurgitation (MR) is a condition which occurs when the heart's mitral valve does not close tightly and blood flows backward in the heart. To compensate for the MR, the heart muscle must increase its contraction, putting extra burden on the left ventricle of the heart and lungs. Eventually, this burden can cause other problems, such as stroke, sudden death, irregular heartbeat, increasing damage to the heart muscle or the inability to maintain adequate systemic circulation of blood. The prevalence of MR increases with age. Currently, surgical management is a well-established pathway for patients in Australia, but typically many patients do not undergo open surgery because of their high-risk status which can include advanced age or other comorbidities.

In April 2020, the Medical Services Advisory Committee (MSAC) supported public funding for TMVr with MitraClip for patients with mitral regurgitation who are unable to or are at high-risk for open heart surgery (MSAC assessment 1192.3).

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The Determination also lists two items for TMVr by permanent coaptation of the heart's mitral valve by using the Mitraclip system (items 38461 and 38463). A service under these items is to be provided if the patient has been assessed by a TMVr suitability case conference (under items 6082 or 6084) as having an unacceptably high risk of surgical mitral valve replacement, and has been recommended for this service. A service under items 38461 and 38463 can only be provided by a cardiothoracic surgeon or an interventional cardiologist, who is accredited by Cardiac Accreditation Services Limited, and can only be provided in a clinically suitable TMVr hospital. These services can only be provided once every five years.

The Government agreed to this MSAC decision in the 2021-22 Budget as part of the *Guaranteeing Medicare — changes to the Medicare Benefits Schedule* measure.

## **Human rights implications**

This instrument engages Articles 9 and 12 of the International Covenant on Economic Social and Cultural Rights (ICESCR), specifically the rights to health and social security.

### *The Right to Health*

The right to the enjoyment of the highest attainable standard of physical and mental health is contained in Article 12(1) of the ICESCR. The UN Committee on Economic Social and Cultural Rights (the Committee) has stated that the right to health is not a right for each individual to be healthy, but is a right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.

The Committee reports that the *'highest attainable standard of health'* takes into account the country's available resources. This right may be understood as a right of access to a variety of public health and health care facilities, goods, services, programs, and conditions necessary for the realisation of the highest attainable standard of health.

### *The Right to Social Security*

The right to social security is contained in Article 9 of the ICESCR. It requires that a country must, within its maximum available resources, ensure access to a social security scheme that provides a minimum essential level of benefits to all individuals and families that will enable them to acquire at least essential health care. Countries are obliged to demonstrate that every effort has been made to use all resources that are at their disposal in an effort to satisfy, as a matter of priority, this minimum obligation.

The Committee reports that there is a strong presumption that retrogressive measures taken in relation to the right to social security are prohibited under ICESCR. In this context, a retrogressive measure would be one taken without adequate justification that had the effect of reducing existing levels of social security benefits, or of denying benefits to persons or groups previously entitled to them. However, it is legitimate for a Government to re-direct its limited resources in ways that it considers to be more effective at meeting the general health needs of all society, particularly the needs of the more disadvantaged members of society.

### Analysis

This instrument advances the right to health and the right to social security by listing four new items which will enable patients who have symptomatic moderate-severe or severe degenerative (primary) mitral valve regurgitation, or symptomatic moderate-severe or severe functional (secondary) mitral valve regurgitation, but are unable to undergo open surgery, to manage this condition by accessing a less invasive approach through transcatheter repair with the MitraClip system.

## **Conclusion**

This instrument is compatible with human rights as it maintains the right to health and the right to social security.

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