#### **EXPLANATORY STATEMENT**

## Health Insurance Act 1973

# Health Insurance (Section 3C General Medical Services – Transcatheter Aortic Valve Implantation) Amendment (No. 1) Determination 2024

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 2021*.

This instrument relies on subsection 33(3) of the Acts Interpretation Act 1901 (AIA). Subsection 33(3) of the AIA provides that where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character (including rules, regulations or by-laws), the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument.

# **Purpose**

The purpose of the *Health Insurance (Section 3C General Medical Services – Transcatheter Aortic Valve Implantation) Amendment (No. 1) Determination 2024* (the Amendment Determination) is to amend Transcatheter Aortic Valve Implantation (TAVI) items 38514 and 38522 to update the circumstances in which the items apply.

From 1 November 2024, the *Health Insurance Legislation Amendment (2024 Measures No. 4) Regulations 2024* will make changes to Medicare Benefits Schedule (MBS) item 90300 to allow patients to receive a Medicare benefit when a cardiothoracic surgeon provides standby surgical back up for non-cardiac surgeons undertaking TAVI services described in items 38514 and 38522.

The Amendment Determination will make minor amendments to TAVI items 38514 and 38522 from 1 November 2024, which will require:

- services under the items (including valvuloplasty) to be performed in a facility
  where cardiothoracic surgery is available and a thoracotomy can be performed
  immediately and without transfer; and
- a cardiothoracic surgeon to attend services under either of the items, if the service is performed by an interventional cardiologist.

These amendments will provide increased safety for patients if complications occur during intermediate or low surgical risk TAVI services.

These amendments were agreed to by Government in the 2024-25 Budget under the Strengthening Medicare – an effective and clinically appropriate Medicare Benefits Schedule measure.

## Consultation

These changes were requested by the Australian and New Zealand Society of Cardiac and Thoracic Surgeons (ANZSCTS) and approved by the Medical Services Advisory Committee (MSAC) Executive at their 4 December 2023 meeting. The Department of Health and Aged Care undertook consultation with the ANZSCTS and the Cardiac Society of Australia and New Zealand who were both supportive of the changes.

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

The Amendment Determination commences on 1 November 2024.

Details of the Amendment Determination are set out in the <u>Attachment</u>.

<u>Authority</u>: Subsection 3C(1) of the *Health Insurance Act 1973* 

Details of the Health Insurance (Section 3C General Medical Services – Transcatheter Aortic Valve Implantation) Amendment (No. 1) Determination 2024

## Section 1 – Name

Section 1 provides for the Amendment Determination to be referred to as the *Health Insurance* (Section 3C General Medical Services – Transcatheter Aortic Valve Implantation) Amendment (No. 1) Determination 2024 (the Amendment Determination).

# Section 2 – Commencement

Section 2 provides for the Amendment Determination to commence on 1 November 2024.

# Section 3 – Authority

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

# Section 4 – Schedules

Section 4 provides that each instrument that is specified in a Schedule to this Amendment Determination is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this Amendment Determination has effect according to its terms.

# Schedule 1 – Amendments

Health Insurance (Section 3C General Medical Services – Transcatheter Aortic Valve Implantation) Determination 2018

**Items 1 and 2** amend Transcatheter Aortic Valve Implantation (TAVI) items 38514 and 38522 to include the requirement that:

- services under these items are performed in a facility where cardiothoracic surgery is available and a thoracotomy can be performed immediately and without transfer; and
- a cardiothoracic surgeon is in attendance during the service, if it is performed by an interventional cardiologist.

This amendment supports the amendments to Medicare Benefits Schedule (MBS) item 90300, which specify that a service under the item may be claimed when a cardiothoracic surgeon provides standby surgical back up for non-cardiac surgeons undertaking TAVI services described in items 38514 and 38522. The amendment to item 90300 will be implemented by the *Health Insurance Legislation Amendment (2024 Measures No. 4) Regulations 2024*, which will commence on 1 November 2024.

# 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 Aortic Valve Implantation) Amendment (No. 1) Determination 2024

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 purpose of the *Health Insurance (Section 3C General Medical Services – Transcatheter Aortic Valve Implantation) Amendment (No. 1) Determination 2024* (the Amendment Determination) is to amend Transcatheter Aortic Valve Implantation (TAVI) items 38514 and 38522 to update the circumstances in which the items apply.

From 1 November 2024, the *Health Insurance Legislation Amendment (2024 Measures No. 4) Regulations 2024* will make changes to Medicare Benefits Schedule (MBS) item 90300 to allow patients to receive a Medicare benefit when a cardiothoracic surgeon provides standby surgical back up for non-cardiac surgeons undertaking TAVI services described in items 38514 and 38522.

The Amendment Determination will make minor amendments to TAVI items 38514 and 38522 from 1 November 2024, which will require:

- services under the items (including valvuloplasty) to be performed in a facility where cardiothoracic surgery is available and a thoracotomy can be performed immediately and without transfer; and
- a cardiothoracic surgeon to attend services under either of the items, if the service is performed by an interventional cardiologist.

These amendments will provide increased safety for patients if complications occur during intermediate or low surgical risk TAVI services.

These amendments were agreed to by Government in the 2024-25 Budget under the *Strengthening Medicare – an effective and clinically appropriate 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.

# The right of equality and non-discrimination

The rights of equality and non-discrimination are contained in articles 2, 16 and 26 of the International Covenant on Civil and Political Rights (ICCPR). Article 26 of the ICCPR requires that all persons are equal before the law, are entitled without any discrimination to the equal protection of the law and in this respect, the law shall prohibit any discrimination and guarantee to all persons equal and effective protection against discrimination on any ground such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.

#### Analysis

This instrument maintains the rights to health and social security and the right of equality and non-discrimination by continuing to support access to Medicare benefits for patients requiring treatment for symptomatic severe aortic stenosis, and by providing additional increased safety precautions for patients receiving this treatment.

#### Conclusion

This instrument is compatible with human rights as it maintains the right to health, the right to social security and the right of equality and non-discrimination.

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