

EXPLANATORY STATEMENT

Health Insurance Act 1973

Health Insurance (Section 3C General Medical Services – Transcatheter Aortic Valve Implantation) Amendment (Limit to Intermediate and High Risk Surgical Patients) 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 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 (Limit to Intermediate and High Risk Surgical Patients) Determination 2021* (the Amendment Determination) is to amend the *Health Insurance (Section 3C General Medical Services – Transcatheter Aortic Valve Implantation) Determination 2018* (the Principal Determination) to amend transcatheter aortic valve implantation (TAVI) procedural item 38495 and introduce new item 38514 to reflect the two separate clinical populations that have been supported by the MSAC for the TAVI procedure.

A TAVI procedure is performed where a patient has severe symptomatic aortic stenosis and is at risk of complications from surgical aortic valve replacement (open-heart surgery). Generally, patients with severe aortic stenosis fall into three surgical risk categories being low, intermediate and high risk. At this point in time TAVI procedures will only be available for intermediate and high surgical risk patients who are identified by specific clinical criteria.

The Amendment Determination amends TAVI item 38495 to prescribe that the service applies to a patient at high risk of complications for surgery and apply a co-claiming restriction against new item 38514. This change also clarifies that a service under item 38514 must be provided in a hospital setting only.

New TAVI item 38514 is also introduced for the treatment of symptomatic severe aortic stenosis in a patient at intermediate risk of complications for surgery. A service under 38514 must include all intraoperative diagnostic imaging provided for the TAVI procedure

and must be provided in an eligible hospital on an eligible patient by an eligible practitioner. The eligibility criteria for this service is defined within the Principal Determination.

New item 38514 provides patients who are at intermediate risk of complications for surgery with a less invasive option for their aortic stenosis, which severely affects a person's activities of daily living. New item 38514 cannot be claimed if a service to which item 38514 or 38495 has been provided to the patient within the previous five years and must be provided in a hospital setting only.

These changes recognise the differing levels of complexity and safety risk of TAVI procedures between patients with a high or intermediate risk of complications for surgery and provides access to a safe, effective, and minimally invasive treatment option for a patient cohort that suffers severe dysfunction as a result of aortic stenosis.

These changes were recommended by the Medical Services Advisory Committee (MSAC) at their November 2020 and March-April 2021 meetings. MSAC reviews new or existing medical services or technology and makes recommendations as to the circumstances under which public funding should be supported. This includes the listing of new items, or amendments to existing items on the MBS.

Consultation

Consultation was undertaken by the Department with the Australian and New Zealand Society of Cardiac and Thoracic Surgeons, Australian Medical Association, the Australian Private Hospitals Association, the Cardiac Society of Australia and New Zealand and Private Health Australia, who were broadly supportive of the changes.

Details of the Amendment Determination are set out in the Attachment.

The Amendment Determination commences on 1 March 2022.

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

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

ATTACHMENT

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

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 (Limit to Intermediate and High Risk Surgical Patients) Determination 2021*.

Section 2 – Commencement

Section 2 provides that the Amendment Determination commences on 1 March 2022.

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

Amendment items 1 amends the definitions of ‘TAVI Case Conference’ and ‘TAVI Hospital’ to include a reference to new transcatheter aortic valve implantation (TAVI) procedural item 38514 (refer to **amendment item 2** of the Amendment Determination). This change is considered minor and administrative in nature.

Amendment item 2 amends the definition of ‘TAVI Patient’ to include patients who are at an intermediate risk for surgical aortic valve replacement and include a reference to new transcatheter aortic valve implantation (TAVI) procedural item 38514. This change is considered minor and administrative in nature.

Amendment items 3 and 4 amend section 7, which provides for the application of item 38495, to include a reference to new transcatheter aortic valve implantation (TAVI) procedural item 38514. This change is considered minor and administrative in nature.

Amendment item 5 inserts new section 8, which provides for the meaning of the symbol “(H)”. Consistent with other MBS items, (H) denotes that the service described within an item which contains the symbol applies only to a service performed or provided in a hospital. This change

does not affect the service and clarifies that a service under items 38495 and 38514 are to be provided in a hospital setting only.

Amendment item 6 repeals and replaces TAVI procedural item 38495 to amend the item and insert new TAVI procedural item 38514.

Item 38495 will be amended to prescribe that the item applies to a patient who is at high risk of complication for surgery, apply a co-claiming restriction against new item 38514 and clarify that the service is to be provided in a hospital setting only. This change recognises the higher complexity of the service when performed on a patient who is considered a high risk for surgery.

New item 38514 is for the treatment of symptomatic severe aortic stenosis by TAVI in a patient at intermediate risk of complication for surgery. A service under 38514 includes all intraoperative diagnostic imaging provided for the TAVI procedure and must be provided in a TAVI Hospital on a TAVI Patient by a TAVI Practitioner.

New item 38514 provides patients who are at intermediate risk of complications for surgery with a less invasive option for their aortic stenosis, which severely affects a person's activities of daily living. New item 38514 cannot be claimed if a service to which item 38514 or 38495 has been provided to the patient within the previous five years and must be provided in a hospital setting only.

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 (Limit to Intermediate and High Risk Surgical Patients) 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

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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 right to health, the right to social security and the right of equality and non-discrimination by providing patients at intermediate risk for surgery access to a less invasive subsidised medical service for their aortic stenosis.

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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