

EXPLANATORY STATEMENT

Health Insurance Act 1973

Health Insurance (Section 3C General Medical Services – Transcatheter Aortic Valve Implantation) Amendment (Low Risk Surgical Patients and CEP Device) Determination 2022

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 (Low Risk Surgical Patients and CEP Device) Determination 2022* (the Amendment Determination) is to amend the *Health Insurance (Section 3C General Medical Services – Transcatheter Aortic Valve Implantation) Determination 2018* (the Principal Determination) to introduce two new items (38522 and 38523) and amend transcatheter aortic valve implantation (TAVI) procedural items 38495 and 38514.

A TAVI procedure is performed where a patient has symptomatic severe aortic stenosis or symptomatic severe native calcific aortic stenosis and is at risk of complications from surgical aortic valve replacement (open-heart surgery). Generally, patients with severe aortic stenosis or symptomatic severe native calcific aortic stenosis fall into three surgical risk categories being low, intermediate and high risk. From 1 July 2022, TAVI procedures will be available for low surgical risk patients with symptomatic severe native calcific aortic stenosis as well as intermediate and high surgical risk patients with symptomatic severe aortic stenosis.

New TAVI item 38522 is introduced for the treatment of symptomatic severe native calcific aortic stenosis in a patient at low risk of complications for open surgical aortic replacement. A service under 38522 must be provided in an eligible hospital on an eligible patient by an eligible practitioner and must include all intraoperative diagnostic imaging provided for the TAVI procedure, performed by the same eligible practitioner. The eligibility criteria for this service is defined within the Principal Determination.

New item 38522 provides patients who are at low 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 38522 cannot be claimed if a service to which item 38522, 38514 or 38495 has been provided to the patient within the previous five years and must be provided in a hospital setting only.

New item 38523 is introduced for the insertion of a dual-filter (multi-filter) cerebral embolic protection (CEP) device when a patient is undergoing a TAVI procedure. A service under 38523 is available to TAVI patients in all risk categories and will improve health outcomes for TAVI patients by reducing the number of TAVI related embolic ischaemic strokes which is a type of cerebrovascular accident (CVA). If a service under item 38523 is performed by the practitioner performing the TAVI procedure, this service must also include all intraoperative diagnostic imaging provided for the CEP and TAVI procedures, performed by the same eligible practitioner. If the service is performed by a different practitioner, the service does not need to include all intraoperative diagnostic imaging.

The Amendment Determination also amends TAVI items 38495 and 38514 to apply a co-claiming restriction against new item 38522.

These changes recognise the differing levels of complexity and safety risk of TAVI procedures between patients with a high, intermediate or low 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 July 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 Medical Benefits Schedule (MBS).

The Amendment Determination also implements annual fee indexation by increasing the schedule fees of the items in Schedule 1 by 1.6 per cent. This increase of the schedule fees reflects the Government's policy regarding Medicare indexation and means that patients will receive an increased Medicare benefit for these services.

Consultation

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

No consultation was undertaken regarding annual indexation, as this change continues business-as-usual implementation of the Government's policy on Medicare indexation, which is expected by stakeholders to be applied on 1 July of each year.

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

The Amendment Determination commences on 1 July 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

Details of the Health Insurance (Section 3C General Medical Services – Transcatheter Aortic Valve Implantation) Amendment (Low Risk Surgical Patients and CEP Device) Determination 2022

Section 1 – Name

Section 1 provides for the Amendment Determination to be referred to as *Health Insurance (Section 3C General Medical Services – Transcatheter Aortic Valve Implantation) Amendment (Low Risk Surgical Patients and CEP Device) Determination 2022*.

Section 2 – Commencement

Section 2 provides that the Amendment Determination commences on 1 July 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 – TAVI Amendments

Schedule 1 of the Amendment Determination amends the *Health Insurance (Section 3C General Medical Services – Transcatheter Aortic Valve Implantation) Determination 2018* (Principal Determination).

Amendment item 1 amends the definitions of ***TAVI Case Conference*** and ***TAVI Hospital*** in subsection 5(1) to include a reference to new transcatheter aortic valve implantation (TAVI) procedural item 38522 (refer to **amendment item 6** of the Amendment Determination). This change is considered minor and administrative in nature.

Amendment item 2 amends the definition of ***TAVI Patient*** in subsection 5(1) to include patients who are at a low risk for surgical aortic valve replacement and include a reference to new TAVI procedural item 38522. This change is considered minor and administrative in nature.

Amendment items 3 and 4 amend section 7, which provides for the application of items 38495 and 38514, to include a reference to new TAVI procedural item 38522. This change is considered minor and administrative in nature.

Amendment items 5 and 6 amend the schedule fees for items 6080 and 6081, increasing the schedule fees of the items by 1.6 per cent to implement annual fee indexation.

Amendment item 7 repeals and replaces TAVI procedural items 38495 and 38514 to amend these items and inserts new items 38522 and 38523.

TAVI procedural items 38495 and 38514 are amended to apply a co-claiming restriction against new item 38522. The schedule fees for items 38495 and 38514 are also increased by 1.6 per cent to implement annual fee indexation.

New item 38522 is for the treatment of symptomatic severe aortic stenosis in a patient at low risk of complications for surgery. A service under 38522 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 38522 provides patients who are at low 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 38522 cannot be claimed if a service to which item 38522, 38514 or 38495 has been provided to the patient within the previous five years and must be provided in a hospital setting only.

New item 38523 is for the insertion of a dual-filter (multi-filter) cerebral embolic protection (CEP) device when a patient is undergoing a TAVI procedure. A service under 38523 is available to TAVI patients in all risk categories and will improve health outcomes for TAVI patients by reducing the number of TAVI related cerebrovascular accidents (CVA), commonly known as strokes. If a service under item 38523 is performed by the practitioner performing the TAVI procedure, this service must also include all intraoperative diagnostic imaging provided for the CEP and TAVI procedures, performed by the same eligible practitioner. If the service is performed by a different practitioner, the service does not need to include all intraoperative diagnostic imaging.

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 (Low Risk Surgical Patients and CEP Device) Determination 2022

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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These changes were recommended by the Medical Services Advisory Committee (MSAC) at their July 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 Medical Benefits Schedule (MBS).

The Amendment Determination also implements annual fee indexation by increasing the schedule fees of the items in Schedule 1 by 1.6 per cent. This increase of the schedule fees reflects the Government's policy regarding Medicare indexation and means that patients will receive an increased Medicare benefit for these services.

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 advances the rights to health and social security and the right of equality and non-discrimination by providing access to TAVI procedures for patients at low risk of complications for surgical aortic valve replacement (open-heart surgery) and services for implanting CEP devices. Services under item 38522 provide patients who are at low risk of complications for surgery with a less invasive option for their aortic stenosis, which severely affects a person's activities of daily living. This instrument also advances the rights to health and social security and the right of equality and non-discrimination by implementing annual indexation for these new and existing TAVI related services.

Conclusion

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

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