

EXPLANATORY STATEMENT

Health Insurance Act 1973

Health Insurance (Section 3C Co-Dependent Pathology Services) Amendment (No. 2) 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 pathology services table (the PST) shall, in specified circumstances and for specified statutory provisions, be treated as if it were specified in the PST.

The Table is set out in the regulations made under subsection 4A of the Act. The most recent version of the regulations is the *Health Insurance (Pathology Services Table) Regulations 2020*.

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 Co-Dependent Pathology Services) Amendment (No. 2) Determination 2024* (the Amendment Determination) is to amend co-dependent Medicare Benefits Schedule (MBS) items in the *Health Insurance (Section 3C Co-Dependent Pathology Services) Determination 2018* (the Principal Determination) from 1 January 2025. The amendments to the Principal Determination will implement recommendations made by the Medical Services Advisory Committee (MSAC) and Pharmaceutical Benefits Advisory Committee.

From 1 January 2025, MBS item 73295 for breast cancer gene 1 and 2 (BRCA) mutations testing will be amended to support testing in patients with ovarian, fallopian tube or peritoneal cancer and patients with breast cancer. Currently, breast cancer patients seeking testing under item 73295 must meet certain clinical criteria as listed in the item descriptor. The amendments to item 73295 will remove these requirements to allow testing in all eligible breast cancer patients.

Item 73295 will also be amended to support determining patient eligibility for any relevant treatment under the Pharmaceutical Benefits Schedule (PBS). Currently, item 73295 is limited to determining patient eligibility for PBS treatment with poly (adenosine diphosphate [ADP]-ribose) polymerase (PARP) inhibitors. The amendment to item 73295 will enable it to be used to identify patients suitable for future relevant PBS listed treatments.

Additionally, from 1 January 2025, MBS items 73303 and 73304 for BRCA mutation testing of patients with metastatic castration-resistant prostate cancer will be amended to support determining patient eligibility for any relevant treatment under the PBS. Currently, items 73303 and 73304 are limited to determining patient eligibility for PBS treatment

with olaparib. The amendment to items 73303 and 73304 will enable them to be used to identify patients suitable for the drug talazoparib, which will be listed on the PBS from 1 January 2025, or, for other relevant treatments which may be listed on the PBS in the future.

Consultation

For the amendments to item 73295, consultation was undertaken with the Medical Oncology Group of Australia (MOGA) via the MSAC application process. MOGA indicated that they were supportive of the amendment to item 73295.

For the amendments to items 73303 and 73304, consultation was undertaken with key stakeholders via the MSAC application process and feedback broadly supported the amendments. Consultation input was received from:

- Public Pathology Australia;
- The Urological Society of Australia and New Zealand; and
- Australian Genomics.

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

The Amendment Determination commences on 1 January 2025.

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

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

ATTACHMENT

Details of the *Health Insurance (Section 3C Co-Dependent Pathology Services) Amendment (No. 2) Determination 2024*

Section 1 – Name

Section 1 provides for the Amendment Determination to be referred to as the *Health Insurance (Section 3C Co-Dependent Pathology Services) Amendment (No. 2) Determination 2024* (the Amendment Determination).

Section 2 – Commencement

Section 2 provides for the Amendment Determination to commence on 1 January 2025.

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

Schedule 1 amends the *Health Insurance (Section 3C Co-Dependent Pathology Services) Determination 2018*.

Item 1 amends MBS item 73295 to remove the requirement for breast cancer patients to meet certain criteria (i.e. they must have triple negative early breast cancer, or, hormone receptor positive, *HER2*-negative, early breast cancer with one or more high-risk characteristics) to be eligible for testing of breast cancer gene 1 and 2 (BRCA) mutations under item 73295. **Item 1** also amends MBS item 73295 to enable it to be used to identify patient suitability for any relevant Pharmaceutical Benefits Schedule (PBS) listing, rather than just for treatment with a poly (adenosine diphosphate [ADP]-ribose) polymerase (PARP) inhibitor.

Items 2 and 3 amend MBS items 73303 and 73304 to enable the items to be used to identify patient suitability for any relevant PBS listing, rather than just for treatment with olaparib.

Statement of Compatibility with Human Rights

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

*Health Insurance (Section 3C Co-Dependent Pathology Services) Amendment (No. 2)
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

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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 advances the rights to health and social security and the right of equality and non-discrimination by ensuring patients have access to clinically relevant Medicare benefits by removing requirements for breast cancer patients to meet certain criteria to access breast cancer gene 1 and 2 (BRCA) testing services, and, to support determining patient eligibility for relevant treatments under the Pharmaceutical Benefits Schedule (PBS).

Conclusion

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

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