

EXPLANATORY STATEMENT

Health Insurance Act 1973

Health Insurance (Section 3C Co-Dependent Pathology Services) Amendment Determination (No. 2) 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 pathology 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 section 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 Determination (No. 2) 2022* (the Amendment Determination) is to introduce two new items for BRCA1 and BRCA2 somatic or germline testing for people living with metastatic castration resistant prostate cancer for the purposes of accessing the chemotherapy drug olaparib under the Pharmaceutical Benefits Scheme (PBS).

At its November 2021 meeting, the Pharmaceutical Benefits Advisory Committee (PBAC) supported the listing of olaparib for the treatment of metastatic castration-resistant prostate cancer in patients with BRCA1 or BRCA2 pathogenic gene variants.

Following the PBAC decision, the Medical Services Advisory Committee (MSAC) recommended a new MBS item be introduced for testing of BRCA1 and BRCA2 pathogenic or likely pathogenic gene variants in tumour tissue for patients with metastatic castration-resistant prostate cancer to determine their eligibility for olaparib treatment at its November 2021 meeting. MSAC recommended this item should also include germline testing where tumour testing had failed. The Amendment Determination introduces this service under new item 73303.

At the same meeting, MSAC also supported a new MBS item for testing of germline BRCA1 and BRCA2 pathogenic or likely pathogenic gene variants where testing of tumour tissue is not feasible for patients with metastatic castration-resistant prostate cancer to determine their eligibility for olaparib treatment. This service is available under new item 73304.

The Amendment Determination will amend the *Health Insurance (Section 3C Co-Dependent Pathology Services) Determination 2018* (the Principal Determination) to introduce new items 73303 and 73304 from 1 April 2022.

Consultation

As part of the MSAC process, consultation was undertaken with expert stakeholders, including the Royal College of Pathologists of Australasia (RCPA). Four responses were received through this targeted consultation process, including one from the RCPA, one from a pathology provider and two from consumer groups. The consultation feedback was generally supportive.

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

The Amendment Determination commences on 1 April 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 Co-Dependent Pathology Services) Amendment Determination (No. 2) 2022Section 1 – Name

Section 1 provides for the Amendment Determination to be referred to as the Health Insurance (Section 3C Co-Dependent Pathology Services) Amendment Determination (No. 2) 2022

Section 2 – Commencement

Section 2 provides that the Amendment Determination commences on 1 April 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 Co-Dependent Pathology Services) Determination 2018***

Amendment item [1] introduces new items 73303 and 73304 for BRCA1 and BRCA2 somatic or germline testing for people living with metastatic castration resistant prostate cancer for the purposes of accessing the chemotherapy drug olaprib under the Pharmaceutical Benefits Scheme.

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 Determination (No. 2) 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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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 right to health, the right to social security and the right of equality and non-discrimination by enabling patient access to subsidised testing for BRCA1 and BRCA2 pathogenic gene variants for patients with metastatic castration-resistant prostate cancer. This change will also enable patients with a detected pathogenic or likely pathogenic gene variant to be eligible for access to olaparib under the Pharmaceutical Benefits Scheme.

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. This instrument advances the right to health by expanding subsidised genetic testing to allow access to medication listed on the Pharmaceutical Benefits Scheme.

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