

EXPLANATORY STATEMENT

Health Insurance Act 1973

Health Insurance (Section 3C Co-Dependent Pathology) Amendment (No. 3) Determination 2023

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 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. 3) Determination 2023* (the Amendment Determination) is to amend the *Health Insurance (Section 3C Co-Dependent Pathology Services) Determination 2018* (the Principal Determination) to insert new item 73307 from 1 January 2024.

The new item will enable Medicare benefits to be paid for homologous recombination deficiency (HRD) testing in the patient's tumour tissue to establish HRD status (including *BRCA1* and *BRCA2* status) of patients with advanced or metastatic high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer.

Currently there is MBS funding for tumour *BRCA1* or *BRCA2* testing in patients with advanced, high grade serous or high grade epithelial ovarian, fallopian tube or primary peritoneal cancer, for access to poly-ADP ribose polymerase inhibitor therapies (PARP inhibitors) listed under the Pharmaceutical Benefits Scheme (PBS). HRD testing will identify an additional subgroup of patients who may benefit from or are likely to respond to treatments with PARP inhibitors listed under the PBS. A positive homologous recombination deficiency status (in the absence of a pathogenic *BRCA1* or *BRCA2* variant) would support access to PARP inhibitors listed under the PBS.

Consultation

Consultation was undertaken with peak bodies, including the Royal College of Pathologists of Australasia (RCPA), Australian Genomics, Pink Hope and Ovarian Cancer Australia.

The Medical Services Advisory Committee (MSAC) noted high levels of support from clinicians for access to HRD testing. MSAC advised that treatments for this group of patients comprised an area of unmet need, as patients currently face poor outcomes.

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

The Amendment Determination commences on 1 January 2024.

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) Amendment (No. 3) Determination 2023*Section 1 – Name

Section 1 provides for the Amendment Determination to be referred to as the *Health Insurance (Section 3C Co-Dependent Pathology) Amendment (No. 3) Determination 2023* (the Amendment Determination).

Section 2 – Commencement

Section 2 provides for the Amendment Determination to commence on 1 January 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 Co-Dependent Pathology Services) Determination 2018*

Item 1 introduces item 73307 which will enable Medicare benefits to be paid for the testing of tumor tissue from a patient with advanced or metastatic high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer, where the test has been requested by a specialist or consultant physician, to determine homologous recombination deficiency (HRD) status, including *BRCA1* or *BRCA2* status, for access to treatment with poly-ADP ribose polymerase inhibitor therapies (PARP inhibitors) under the Pharmaceutical Benefits Scheme (PBS).

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) Amendment (No. 3)
Determination 2023*

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 Amendment Determination

The purpose of the *Health Insurance (Section 3C Co-Dependent Pathology Services) Amendment (No. 3) Determination 2023* (the Amendment Determination) is to amend the *Health Insurance (Section 3C Co-Dependent Pathology Services) Determination 2018* (the Principal Determination) to insert new item 73307 from 1 January 2024.

The new item will enable Medicare benefits to be paid for homologous recombination deficiency (HRD) testing in the patient's tumour tissue to establish HRD status (including *BRCA1* and *BRCA2* status) of patients with advanced or metastatic high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer. HRD testing will identify an additional subgroup of patients who may benefit from or are likely to respond to treatments with poly-ADP ribose polymerase inhibitor therapies (PARP inhibitors) listed under the Pharmaceutical Benefits Scheme (PBS).

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 enabling Medicare benefits to be paid to patients who need to access HRD testing to determine if they may benefit from PARP inhibitor therapies under the PBS.

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.

Mary Warner
Assistant Secretary
Diagnostic Imaging and Pathology Branch
Medicare Benefits and Digital Health Division
Health Resourcing Group
Department of Health and Aged Care