

EXPLANATORY STATEMENT

Health Insurance Act 1973

Health Insurance (Section 3C Co-Dependent Pathology Services) Amendment Determination (No. 4) 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. 4) 2022* (the Amendment Determination) is to amend the *Health Insurance (Section 3C Co-Dependent Pathology Services) Determination 2018* (Co-Dependent Pathology Services Determination). This Amendment Determination amends items 73295 and 73301 to replace the specific drug name of 'olaparib' with the name of the class of drugs 'poly (adenosine diphosphate [ADP]-ribose) polymerase (PARP) inhibitor'. PARP inhibitors are a type of targeted cancer drug and include the drugs olaparib and niraparib.

At its March 2022 meeting, the Pharmaceutical Benefits Advisory Committee (PBAC) supported the listing of niraparib on the Pharmaceutical Benefits Scheme (PBS) for the treatment of high grade epithelial ovarian, fallopian tube or primary peritoneal cancer in patients with BRCA1 or BRCA2 pathogenic gene variants, who are either completely or partially responsive to 1L platinum-based chemotherapy. The PBAC recommendation for listing would require an eligible patient to have evidence of a BRCA1 or BRCA2 pathogenic gene. The amendment permits MBS items 73295 and 73301 to be used to determine eligibility for not only olaparib and niraparib, but also other PARP inhibitors that may be approved in the future by PBAC for listing on the PBS in regard to the treatment of the conditions listed in MBS items 73295 and 73301. These amendments were supported by the Medical Services Advisory Committee (MSAC) Executive at its April 2022 meeting.

The Amendment Determination will enable Medicare benefits to be payable for testing to determine BRCA1 or BRCA2 status for eligibility to access niraparib in addition to olaparib under the PBS from 1 September 2022.

Consultation

MSAC reviews new or existing medical services or technology, and the circumstances under which public funding should be supported through listing on the MBS. This includes the listing of new items, or amendments to existing items on the MBS.

Peak pathology bodies, the Royal College of Pathologists of Australasia, Australian Pathology and Public Pathology Australia were consulted in regard to this amendment.

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

The Amendment Determination commences on 1 September 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. 4) 2022*

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 Determination (No. 4) 2022*.

Section 2 – Commencement

Section 2 provides that the Amendment Determination commences on 1 September 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 repeals and replaces items 73295 and 73301 to allow Medicare benefits to be paid for testing a patient's BRCA1 or BRCA2 status to determine eligibility for access to niraparib in addition to olaparib under the PBS, but also other PARP inhibitors that may be approved in the future by PBAC for listing on the PBS in regard to the treatment of the conditions listed in MBS items 73295 and 73301. This change will benefit eligible patients with high grade epithelial ovarian, fallopian tube or primary peritoneal cancer with BRCA1 or BRCA2 pathogenic gene variants, who are either completely or partially responsive 1L platinum-based chemotherapy.

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. 4) 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

The purpose of the *Health Insurance (Section 3C Co-Dependent Pathology Services) Amendment Determination (No. 4) 2022* (the Amendment Determination) is to amend the *Health Insurance (Section 3C Co-Dependent Pathology Services) Determination 2018* (Co-Dependent Pathology Services Determination). This Amendment Determination amends items 73295 and 73301 to replace the specific drug name of 'olaparib' with the name of the class of drugs 'poly (adenosine diphosphate [ADP]-ribose) polymerase (PARP) inhibitor'. PARP inhibitors are a type of targeted cancer drug and includes the drugs olaparib and niraparib.

At its March 2022 meeting, the Pharmaceutical Benefits Advisory Committee (PBAC) supported the listing of niraparib on the Pharmaceutical Benefits Scheme (PBS) for the treatment of high grade epithelial ovarian, fallopian tube or primary peritoneal cancer in patients with BRCA1 or BRCA2 pathogenic gene variants, who are either completely or partially responsive 1L platinum-based chemotherapy. The PBAC recommendation for listing would require an eligible patient to have evidence of a BRCA1 or BRCA2 pathogenic gene. The amendment to items 73295 and 73301 were supported by the Medical Services Advisory Committee (MSAC) Executive at its April 2022 meeting.

The Amendment Determination will enable Medicare benefits to be payable for testing a patient's BRCA1 or BRCA2 status to determine for eligibility for to access niraparib in addition to olaparib under the PBS from 1 September 2022.

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 existing rights to health, the right to social security and the right of equality and non-discrimination by providing patients with access to Medicare benefits for pathology testing for the detection of BRCA1 or BRCA2 pathogenic gene variants in patients living with high grade epithelial ovarian, fallopian tube or primary peritoneal cancer to determine the patient's eligibility for treatment with niraparib 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.

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