

## EXPLANATORY STATEMENT

### *Health Insurance Act 1973*

#### *Health Insurance (Section 3C Co-Dependant Pathology Services) Amendment Determination (No. 1) 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-Dependant Pathology Services) Amendment Determination (No. 1) 2023* (the Determination) is to amend the *Health Insurance (Section 3C Co-Dependent Pathology Services) Determination 2018* from 1 September 2023.

From 1 September 2023, existing Medicare Benefits Schedule (MBS) item 72814 will be amended to expand access to all patients diagnosed with locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC). Currently, item 72814 provides funding for examination of programmed cell death ligand 1 (PD-L1) antibody in tumour material from a patient diagnosed with non-small cell lung cancer or recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx.

The change made by the Determination was recommended by Medical Services Advisory Committee (MSAC) at its March 2023 meeting under MSAC application 1549. This followed the March 2023 Pharmaceutical Benefits Advisory Committee (PBAC) recommendation to list pembrolizumab (Keytruda®) on the Pharmaceutical Benefits Scheme (PBS) for patients with advanced breast cancer, where the PD-L1 status of their tumour material indicates that this may be a suitable treatment option.

Patients with locally recurrent unresectable or metastatic TNBC have a poorer prognosis and limited treatment options compared to other patients with breast cancer. Testing tumour material for PD-L1 status will assist clinicians to determine their patient's eligibility to access treatment with pembrolizumab on the PBS.

Patients with locally recurrent unresectable or metastatic TNBC, who have a PD-L1 combined positive score (CPS) equal to or more than 10 will be able to access treatment using pembrolizumab on the PBS from 1 September 2023.

**Consultation**

The 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.

As part of the MSAC consultation process, consultation has been undertaken with peak medical bodies including the Royal College of Pathologists of Australasia and the Australasian Society for Breast Disease.

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

The Determination commences on 1 September 2023.

Details of the 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-Dependant Pathology Services) Amendment Determination (No. 1) 2023***Section 1 – Name

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

Section 2 – Commencement

Section 2 provides for the Determination to commence on 1 September 2023.

Section 3 – Authority

Section 3 provides that the 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 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 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 the item descriptor for item 72814 to allow patients living with locally recurrent unresectable or metastatic triple-negative breast cancer to access a Medicare benefit for programmed cell death ligand 1 (PD-L1) antibody testing to better inform their treatment options. This amendment will expand the patient population that may receive a service under MBS item 72814 from 1 September 2023 to align with the changes made on the 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-Dependant Pathology Services) Amendment Determination (No. 1) 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 Determination

The purpose of the *Health Insurance (Section 3C Co-Dependant Pathology Services) Amendment Determination (No. 1) 2023* (the Determination) is to amend the *Health Insurance (Section 3C Co-Dependant Pathology Services) Determination 2018* from 1 September 2023.

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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 maintains the rights to health and social security and the right of equality and non-discrimination by ensuring access to publicly subsidised medical services are clinically and cost-effective as intended.

#### **Conclusion**

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

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