

## EXPLANATORY STATEMENT

### *Health Insurance Act 1973*

#### *Health Insurance (Section 3C Co-Dependent Pathology Services) Amendment Determination (No. 1) 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.

Subsection 12(2) of the *Legislation Act 2003* provides a registered legislative instrument may have a commencement date prior to the date of registration (retrospective commencement) if it does not disadvantage a person (other than the Commonwealth) or impose a liability on a person (other than the Commonwealth). Subsection 12(4) of the *Legislation Act 2003* provides the effect of subsection (2) in relation to an instrument is subject to any contrary provision in an Act.

Subsection 3C(2) of the Act expressly excludes subsection 12(2) of the *Legislation Act 2003* from applying to determinations made under section 3C(1) of the Act. However, this instrument will not impose a liability or disadvantage a person other than the Commonwealth, consistent with the intent of *Legislation Act 2003*.

### **Purpose**

The purpose of *Health Insurance (Section 3C Co-Dependent Pathology Services) Amendment Determination (No. 1) 2022* (the Amendment Determination) is to amend item 73338 in the *Health Insurance (Section 3C Co-Dependent Pathology Services) Determination 2018* (the Principal Determination) to allow access to BRAF V600 gene variant testing for patients with metastatic colorectal cancer. This amendment will enable patients with a positive result to the gene variant to be eligible for access to encorafenib under the Pharmaceutical Benefits Scheme (PBS). This amendment supports current pathology practice to report on both rat sarcoma oncogene (RAS) and BRAF V600 mutations as part of tissue pathology assessment for metastatic colorectal cancer.

### **Consultation**

The Medical Services Advisory Committee (MSAC) reviews new or existing medical services or technology and makes recommendations as to the circumstances under which public funding should be supported. This includes the listing of new items, or amendments to existing items under Medicare.

As part of the MSAC process, consultation was undertaken with key stakeholders, including clinical experts and providers, and consumer health representatives. Targeted consultation was undertaken with the Royal College of Pathologists of Australasia, Australian Pathology and Public Pathology Australia on the amendment to item 73338.

Details of the Determination are set out in the Attachment.

The Determination commences immediately after registration. Schedule 1 of the Determination is taken to have commenced retrospectively on 1 January 2022.

The 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. 1) 2022***Section 1 – Name

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

Section 2 – Commencement

Section 2 provides that sections 1 to 4 of the Amendment Determination commences immediately after registration. Schedule 1 of the Amendment Determination is taken to have commenced retrospectively from 1 January 2022.

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***Item 1 – Schedule 1 (cell at item 73338, column 2)**

Item 2 repeals and replaces the column 2 descriptor of item 73338 to expand the service to provide access to BRAF V600 testing to determine eligibility for PBS access to encorafenib in patients with metastatic colorectal cancer (Stage IV).

The updated item descriptor will continue to include services where the test is provided to determine if requirements relating to Kirsten RAS (KRAS) gene variant status for access to cetuximab or panitumumab under the PBS are fulfilled.

## 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. 1) 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 *Health Insurance (Section 3C Co-Dependent Pathology Services) Amendment Determination (No. 1) 2022* (the Amendment Determination) is to amend item 73338 in the *Health Insurance (Section 3C Co-Dependent Pathology Services) Determination 2018* (the Principal Determination) to allow access to BRAF V600 gene variant testing for patients with metastatic colorectal cancer. This amendment will enable patients with a positive result to the gene variant to be eligible for access to encorafenib under the Pharmaceutical Benefits Scheme (PBS). This amendment supports current pathology practice to report on both rat sarcoma oncogene (RAS) and BRAF V600 mutations as part of tissue pathology assessment for metastatic colorectal cancer.

#### **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 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 giving patients access to BRAF V600 mutation testing for patients with metastatic colorectal cancer. This change will also enable patients with a positive result to the gene mutation to be eligible for access to encorafenib 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.

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