

## EXPLANATORY STATEMENT

### *Health Insurance Act 1973*

#### *Health Insurance (Section 3C Co-Dependent Pathology Services) Amendment Determination (No. 7) 2020*

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(1) 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. 7) 2020* (the Determination) is to amend the *Health Insurance (Section 3C Co-Dependent Pathology Services) Determination 2018* to expand Medicare Benefits Schedule (MBS) item 73337 to enable access to medicines identified as an epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor, which will include the drug osimertinib, from 1 January 2021.

Item 73337 commenced on 1 January 2014 for the testing of tumour tissue from a patient diagnosed with non-small lung cancer, in order to determine if the patient meets the requirements relating to the EGFR gene status for access to erlotinib or gefitinib under the Pharmaceutical Benefits Scheme (PBS). On 1 July 2018, item 73337 was amended to expand its scope to cover testing for access to PBS medicine, afatinib.

On 1 January 2021, the drug osimertinib will be listed on the PBS. Osimertinib is one of a group of identified medicines with the drug class name of 'EGFR tyrosine kinase inhibitor'. The PBS currently provides access to three other EGFR tyrosine kinase inhibitors; erlotinib, gefitinib and afatinib, for patients who demonstrate a positive EGFR result.

The Determination will amend item 73337 to expand access to medicines identified as an EGFR tyrosine kinase inhibitor on the PBS from 1 January 2021. This will include access to osimertinib, as well as the currently specified drugs erlotinib, gefitinib and afatinib.

The proposal to amend item 73337 to expand access to medicines identified as an EGFR tyrosine kinase inhibitor, which will include osimertinib, was supported by the Pharmaceutical Benefits Advisory Committee (PBAC) in June 2020 and the Medical Services Advisory Committee (MSAC) in July 2020.

**Consultation**

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 on the MBS.

As part of the MSAC process, consultation was undertaken with key stakeholders, clinical experts and providers, and consumer health representatives.

Details of the Determination are set out in the Attachment.

The Determination commences on 1 January 2021.

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. 7) 2020***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. 7) 2020*.

Section 2 – Commencement

Section 2 provides that the Determination commences on 1 January 2021.

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* (the Principal Determination)

**Item 1 – Schedule 1 (cell at item 73337, column 2)**

Item 1 repeals and replaces the descriptor of item 73337 to enable access to medicines identified as an epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor 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. 7) 2020***

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. 7) 2020* (the Determination) is to amend the *Health Insurance (Section 3C Co-Dependent Pathology Services) Determination 2018* to expand Medicare Benefits Schedule (MBS) item 73337 to enable access to medicines identified as an epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor, which will include new drug osimertinib, from 1 January 2021.

Item 73337 commenced on 1 January 2014 for the testing of tumour tissue from a patient diagnosed with non-small lung cancer, in order to determine if the patient meets the requirements relating to the EGFR gene status for access to erlotinib or gefitinib under the Pharmaceutical Benefits Scheme (PBS). On 1 July 2018, item 73337 was amended to expand its scope to cover testing for access to PBS medicine, afatinib.

On 1 January 2021, the drug osimertinib will be listed on the PBS. Osimertinib is one of a group of identified medicines with the drug class name of 'EGFR tyrosine kinase inhibitor'. The PBS currently provides access to three other EGFR tyrosine kinase inhibitors; erlotinib, gefitinib and afatinib, for patients who demonstrate a positive EGFR result.

The Determination will amend item 73337 to expand access to medicines identified as an EGFR tyrosine kinase inhibitor on the PBS from 1 January 2021. This will include access to osimertinib, as well as the currently specified drugs erlotinib, gefitinib and afatinib.

The proposal to amend item 73337 to expand access to medicines identified as an EGFR tyrosine kinase inhibitor, which will include osimertinib, was supported by the Pharmaceutical Benefits Advisory Committee (PBAC) in June 2020 and the Medical Services Advisory Committee (MSAC) in July 2020.

#### **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.

### Analysis

This instrument advances the right to health and the right to social security by expanding MBS item 73337 to enable patients to access all medicines identified as an epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor under the PBS. This will include access to the drug osimertinib from 1 January 2021.

### **Conclusion**

This instrument is compatible with human rights as it advances the right to health and the right to social security.

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