

EXPLANATORY STATEMENT

Issued by the Authority of the Minister for Health

Health Insurance Act 1973

Health Insurance (Section 3C Co-Dependent Pathology Services) Amendment Determination (No. 1) 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The Table is set out in the regulations made under subsection 4A(1) of the Act, which is repealed and remade each year. The most recent version of the regulations is the *Health Insurance (Pathology Services Table) Regulations 2019*.

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. 1) 2020* (the Determination) is to amend the *Health Insurance (Section 3C Co-Dependent Pathology Services) Determination 2018* to enable the addition of “encorafenib” to MBS item 73336.

Item 73336 commenced on 1 December 2013, to test tumour tissue from a patient with unresectable stage III or stage IV metastatic cutaneous melanoma, in order to determine if the patient meets the requirements relating to *BRAF V600* gene mutation status to access the Pharmaceutical Benefits Scheme (PBS) listed drug dabrafenib. On 1 May 2017, the item was expanded to cover testing for vemurafenib on the PBS. On November 1 2019, the item was amended again, to enable patients with completely resected Stage III metastatic cutaneous melanoma to access PBS funded treatment with dabrafenib, in combination with trametinib.

The Determination will amend item 73336 to omit “dabrafenib or vemurafenib”, and substitute “dabrafenib, vemurafenib or encorafenib” to enable MBS funded *BRAF V600* gene mutation testing to facilitate access to encorafenib under the PBS. The addition of encorafenib to MBS item 73336 will allow an additional treatment option to be available to clinicians in consideration of individual patient circumstances, resulting in optimal care for patients. This proposal was supported by the Medical Services Advisory Committee (MSAC) and the Pharmaceutical Benefits Advisory Committee (PBAC) in November 2018.

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.

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 April 2020.

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) 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. 1) 2020*.

Section 2 – Commencement

Section 2 provides that the Determination commences on 1 April 2020.

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 (item 73336, column 2)

Item 1 amends item 73336 by including the word “encorafenib” to the item descriptor.

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) 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. 1) 2020* (the Determination) is to amend the *Health Insurance (Section 3C Co-Dependent Pathology Services) Determination 2018* to include the addition of “encorafenib” to MBS item 73336.

Item 73336 commenced on 1 December 2013, to test tumour tissue from a patient with unresectable stage III or stage IV metastatic cutaneous melanoma, in order to determine if the patient meets the requirements relating to *BRAF V600* gene mutation status to access the Pharmaceutical Benefits Scheme (PBS) listed drug dabrafenib.

On 1 May 2017, the item was expanded to cover testing for vemurafenib on the PBS. This proposal was supported by the Medical Services Advisory Committee (MSAC) in March 2016 and by the Pharmaceutical Benefits Advisory Committee (PBAC), also in March 2016.

On November 1 2019, the item was amended to enable patients with completely resected Stage III metastatic cutaneous melanoma to access PBS funded treatment with dabrafenib, in combination with trametinib.

The addition of encorafenib was supported by the MSAC in March 2019 and by the PBAC in July 2019. Encorafenib is due to be listed on the PBS on 1 April 2020, for the treatment of advanced melanoma patients who are *BRAF V600* gene mutation positive.

The Determination will amend MBS item 73336 to include encorafenib and will facilitate access to an additional PBS listed treatment option for patients with stage III or stage IV metastatic cutaneous melanoma.

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.

Analysis

This instrument advances the right to health and the right to social security with the addition of encorafenib to MBS item 73336. The addition of encorafenib to MBS item 73336 will facilitate access to an additional PBS listed treatment option for patients with stage III or stage IV metastatic cutaneous melanoma.

There is no change to the proposed MBS fee, costs to the MBS or testing strategy. Utilisation is not expected to increase, as this represents an additional treatment choice in the same patient population.

Conclusion

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

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