EXPLANATORY STATEMENT

Issued by the Authority of the Minister for Health

*Health Insurance Act 1973*

*Health Insurance (Section 3C Co-Dependent Pathology Services) Determination 2018*

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 shall, in specified circumstances and for specified statutory provisions, be treated as if it were specified in the pathology services table.

The pathology services table is set out in the regulations made under subsection 4A(1) of the Act, which is re-made each year. The most recent version of the regulations is the *Health Insurance (Pathology Services Table) Regulations 2018.*

**Purpose**

The *Health Insurance (Section 3C Co-Dependent Pathology Services) Determination 2018* (the Determination) prescribes a table of Medicare Benefits Schedule (MBS) pathology items that can be provided to patients for specified genetic testing to determine eligibility for medications subsidised under the Pharmaceutical Benefits Scheme (PBS), known as co-dependent items.

The purpose of the Determination is to consolidate all co-dependent pathology MBS items (73295, 73332, 73336, 73337, 73338, 73341, 73342 and 73343) from various instruments into a single determination. This will also reduce the administrative burden of tracking each individual co-dependent instrument and to allow co-dependent pathology MBS services to be listed simultaneously with new PBS listings.

The Determination also amends item 73337, which was previously listed in the pathology services table, to expand its scope to cover testing for access to the newly listed PBS medicine, afatinib.

MBS item 73337 currently funds a test of tumour tissue from a patient with diagnosed with non-small cell lung cancer. The test is currently available under the MBS to determine if the requirements relating to epidermal growth factor receptor (EGFR) gene status, for determining a patient’s eligibility for treatment with erlotinib or gefitinib on the PBS.

In November 2013, the Medical Services Advisory Committee (MSAC) supported the addition of afatinib to MBS item 73337 pending the Pharmaceutical Benefits Advisory Committees’ approval of the medicine on the PBS. From 1 May 2018, afatinib was listed on the PBS for this same patient group.

**Consultation**

Consultation on the addition of the medicine (afatinib) in item 73337 occurred as part of the MSAC’s consideration of the application.

As part of the MSAC process, consultation was undertaken with professional bodies, consumer groups, the public and clinical experts for proposals put forward for consideration by the Committee.

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.

No consultation was undertaken on the creation of the Determination as the Determination is only a compilation of existing MBS pathology items that are currently listed in other instruments. The Determination makes no changes to patient access to pathology items.

Details of the Determination are set out in the Attachment.

The Determination commences immediately after the commencement of the *Health Insurance (Pathology Services Table) Regulations 2018*.

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) Determination 2018*

Section 1 – Name of Determination

# Section 1 provides the Determination is the *Health Insurance (Section 3C Co-Dependent Pathology Services) Determination 2018*.

Section 2 – Commencement

Section 2 provides that the Determination commences immediately after the commencement of the *Health Insurance (Pathology Services Table) Regulations 2018*.

Section 3 – Authority

Section 3 provides that the Determination is made under subsection 3C(1) of the *Health Insurance Act 1973*.

Section 4 – Revokes

Section 4 revokes the instruments that contain items 73295, 73336, 73341, 73342 and 73343in order for these items to be listed in the Determination. The relevant instruments that are revoked are the *Health Insurance (Pharmacogenetic Testing – Human Epidermal Growth Factor Receptor 2) Determination 2015;* the *Health Insurance (ALK Gene Testing) Determination 2017;* the *Health Insurance (Section 3C Pathology Services—BRAF Gene Testing) Determination 2017;* the *Health Insurance (Section 3C Pathology Services – BRCA Gene Testing No.2) Determination 2017*

and the *Health Insurance (Section 3C Pathology Services—17p Deletion Testing) Determination 2017*.

Section 5 – Definitions

Section 5 defines terms used in the Determination.

Section 6 – Treatment of relevant services

Section 6 provides that a clinically relevant service provided in accordance with the Determination shall be treated, for relevant provisions of the *Health Insurance Act 1973* and *National Health Act 1953*, and regulations made under those Acts, as if it were both a professional service and a pathology service and as if there were an item specified in the pathology services table for the service. The pathology services table is a table of medical services prescribed under section 4A of the *Health Insurance Act 1973*.

Schedule 1 – Relevant Services

Schedule 1 specifies the pathology service requirements and the associated fees for items 73295, 73332, 73336, 73337, 73338, 73341, 73342 and 73343.

**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)***

***Determination 2018***

This Determination 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 Legislative Instrument**

The *Health Insurance (Section 3C Co-Dependent Pathology Services) Determination 2018* (the Determination) prescribes a table of Medicare Benefits Schedule (MBS) pathology items that can be provided to patients for specified genetic testing to determine eligibility for medications subsidised under the Pharmaceutical Benefits Scheme (PBS), known as co-dependent items.

The purpose of the Determination is to consolidate all co-dependent pathology MBS items (73295, 73332, 73336, 73337, 73338, 73341, 73342 and 73343) from various instruments into a single determination. This will also reduce the administrative burden of tracking each individual co-dependent instrument and to allow co-dependent pathology MBS services to be listed simultaneously with new PBS listings.

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**Human rights implications**

The Regulations engage 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 Determination will maintain and advance the existing rights to health and social security by ensuring access to publicly subsidised health services which are clinically effective and cost-effective.

**Conclusion**

This Determination is compatible with human rights as it has a positive effect on human rights issues.

**Celia Street**

**Assistant Secretary**

**Diagnostic Imaging and Pathology Branch**

**Medical Benefits Division**

**Department of Health**