

## EXPLANATORY STATEMENT

Issued by the Authority of the Minister for Health

*Health Insurance Act 1973*

*Health Insurance (Pathologist-determinable Services) Amendment Determination 2018*

Section 4BA of the *Health Insurance Act 1973* (the Act) provides for the Minister to determine that a particular pathology service, or pathology services included in a class of pathology services, specified in the determination instrument are pathologist-determinable services, after consultation with Royal College of Pathologists of Australasia.

Section 16A of the Act specifies that certain requirements have to be met for the payment of Medicare benefits in relation to pathology services, including the requirement for a pathology service to be requested (subsection 16A(3)). Pathologist-determinable services allow Medicare benefits to be paid for pathology services which are requested and performed by an approved pathology practitioner pathologist for their own patients, or for certain tests which are not requested, but are performed on the basis of information learned from an originally requested service.

Subsection 33(3) of the *Acts Interpretation Act 1901* 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 (Pathologist-determinable Services) Amendment Determination 2018* is to amend the *Health Insurance (Pathologist-determinable Services) Determination 2015* to include a reference to a new pathologist-determinable service item 73344.

The new item is for fluorescent in situ hybridisation (FISH) testing for ROS proto-oncogene 1 (ROS1) rearrangements in patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) to determine access to crizotinib under the Pharmaceutical Benefits Scheme (PBS).

This service was supported by the Medical Services Advisory Committee (MSAC) at its meeting in July 2018, and agreed by Pharmaceutical Benefits Advisory Committee (PBAC) at its meeting in November 2018.

Although pathology service item 73344 is not listed the pathology services table made for the purposes of section 4A(1) of the Act, the *Health Insurance (Section 3C Co-Dependent Pathology Services) Amendment Determination (No. 3) 2018*, deems it to be a pathology service specified in that table. The rendering of that service, subject to requirements being met, allows for Medicare benefits to be payable in relation to that service.

**Consultation**

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

MSAC reviews new or existing medical services or technology, and the circumstances under which public funding should be supported through listing on the Medicare Benefits Schedule (MBS). This includes the listing of new items, or amendments to existing items on the MBS.

Section 4BA of the *Health Insurance Act 1973* requires the Royal College of Pathologists of Australasia (RCPA) be consulted about the inclusion of items in this legislative instrument. The RCPA advised it supported the inclusion of item 73344 as a pathologist-determinable item.

Details of the Determination are set out in the [Attachment](#).

The Determination commences immediately after commencement of the *Health Insurance (Section 3C Co-Dependent Pathology Services) Amendment Determination (No. 3) 2018*.

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

## ATTACHMENT

**Details of the *Health Insurance (Pathologist-determinable Services) Amendment Determination 2018***Section 1 – Name

Section 1 provides for the instrument to be referred to as the *Health Insurance (Pathologist-determinable Services) Amendment Determination 2018*.

Section 2 – Commencement

Section 2 provides that the instrument commences immediately after the commencement of the *Health Insurance (Section 3C Co-Dependent Pathology Services) Amendment Determination (No. 3) 2018*.

Section 3 – Authority

Section 3 provides that the instrument is made under subsection 4BA of the *Health Insurance Act 1973*.

Section 4 – Schedules

Section 4 provides that each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1 – Amendment

Item 1 repeals the table under subsection 5(b)(iii) to insert new item 73344, and to insert a note at the bottom of the table to reference that items 73332, 73336, 73337, 73342 and 73344 are specified in a determination made under subsection 3C(1) of the Act.

## Statement of Compatibility with Human Rights

*Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011*

### ***Health Insurance (Pathologist-determinable Services) Amendment Determination 2018***

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 (Pathologist-determinable Services) Amendment Determination 2018* is to amend the *Health Insurance (Pathologist-determinable Services) Determination 2015* to include a reference to a new pathologist-determinable service item 73344.

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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.

#### Analysis

This instrument advances the right to health and the right to social security by ensuring access to publicly subsidised health services which are clinically effective, safe and cost-effective.

#### **Conclusion**

This instrument is compatible with human rights as it has a positive effect on the right to health and the right to social security.

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