

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. 3) 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 (PST) shall, in specified circumstances and for specified statutory provisions, be treated as if it were specified in the PST.

The PST is set out in the regulations made under subsection 4A(1) of the Act, and is repealed and remade each year.

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 (Section 3C Co-Dependent Pathology Services) Amendment Determination (No. 3) 2018* (the Determination) is to amend the *Health Insurance (Section 3C Co-Dependent Pathology Services) Determination 2018* to provide a legal basis for the payment of Medicare benefits for a test provided under new item 73344.

The new fluorescent in situ hybridisation (FISH) testing is 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 proposal 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 November 2018 meeting.

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.

Details of this instrument are set out in the Attachment.

The instrument commences on 1 January 2019.

The instrument 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. 3) 2018*****Section 1 – Name**

Section 1 provides for the instrument to be referred to as the *Health Insurance (Section 3C Co-Dependent Pathology Services) Amendment Determination (No. 3) 2018*.

Section 2 – Commencement

Section 2 provides that the instrument commences on 1 January 2019.

Section 3 – Authority

Section 3 provides that the instrument 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 – Amendment

The instrument amends the *Health Insurance (Section 3C Co-Dependent Pathology Services) Determination 2018* to include new item 73344.

Item 1 prescribes the fee and item descriptor for new item 73344.

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. 3) 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 (Section 3C Co-Dependent Pathology Services) Amendment Determination (No. 3) 2018* (the Determination) is to amend the *Health Insurance (Section 3C Co-Dependent Pathology Services) Determination 2018* to provide a legal basis for the payment of Medicare benefits for a test provided under new item 73344.

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This proposal 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 November 2018 meeting.

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.

Celia Street
Assistant Secretary
Diagnostic Imaging and Pathology Branch
Medical Benefits Division
Health Financing Group
Department of Health