EXPLANATORY STATEMENT

*Health Insurance Act 1973*

***Health Insurance (Section 3C Co-Dependant Pathology) Amendment (No. 2) Determination 2023***

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 of the Act. The most recent version of the regulations is the *Health Insurance (Pathology Services Table) Regulations 2020* (PST).

This instrument relies on subsection 33(3) of the *Acts Interpretation Act 1901* (AIA). Subsection 33(3) of the AIAprovides 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 *Health Insurance (Section 3C Co-Dependant Pathology) Amendment (No. 2) Determination 2023* (the Determination) amends the *Health Insurance (Section 3C Co‑Dependent Pathology Services) Determination 2018* (the Principal Determination) from 1 November 2023 to introduce three new pathology items to the Medicare Benefits Scheme (MBS) to streamline testing for genetic variants in patients with non-squamous (or histology not otherwise specified) non‑small cell lung cancer (NSCLC). Minor amendments will also be made to align four existing MBS items for single gene tests for NSCLC with the three new items.

The three new items will provide specialists and consultant physicians with the opportunity to request MBS funded, multi-gene panel tests using deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) techniques on tumour tissue samples of patients with new diagnoses of NSCLC, to determine access to Pharmaceutical Benefits Scheme (PBS) listed immunotherapies.

The three new MBS co-dependant pathology items are as follows:

* Item 73437 is a nucleic acid-based multi-gene panel testing service using both DNA and RNA techniques to test for a minimum of four specified gene variants and a minimum of six specified genes to ascertain fusion status;
* Item 73438 is a DNA‑based multi-gene panel testing service to test for a minimum of four specified gene variants; and
* Item 73439 is an RNA-based multi-gene panel testing service of six specified fusion status items.

It is common for some types of cancers to have certain harmful genetic changes that can be used as targets for treatments. For NSCLC, the most common gene variants are in the EGFR, ALK, ROS1 and MET genes. Testing of fusion status of the ALK, ROS1, RET, NTRK1, NTRK2, and NTRK3 genes can also detect harmful variations.

Prior to these amendments, to qualify for MBS funding, patients with NSCLC would need to be tested for these gene variants separately and sequentially to determine if they should receive a certain treatment or not. Medical Services Advisory Committee (MSAC), in its 2022 review of application 1721, found that the methodology of using one or two small panel tests is considered superior in effectiveness and patient safety compared to multiple separate and sequential tests because it requires fewer tumour tissue samples and fewer re-biopsies, resulting in less sample deterioration, faster results, and earlier commencement of targeted treatment of NSCLC.

The Determination also makes minor amendments to align four existing co-dependant pathology MBS items for single gene tests for NSCLC with the three new items. The affected services are: 73337, 73341, 73344, and 73436. The amended item descriptors will remove references to specific drugs or classes of drugs and substitute with references to ‘an immunotherapy listed under the Pharmaceutical Benefits Scheme (PBS)’. The amended descriptors will also restrict co-claiming with the new co-dependent items.

These new items were recommended by MSAC at its November 2022 meeting under MSAC application 1721.

**Consultation**

The Royal College of Pathologists of Australasia (RCPA) was the applicant for the MSAC application and has been consulted as part of the MSAC process. The National Pathology Accreditation Advisory Council (NPAAC) provided advice and assurance to MSAC on the current availability and likely future developments for next generation sequencing panel testing and quality control arrangements for the proposed tests.

The following stakeholders were also consulted and of those who responded, all were supportive of the proposed changes to the MBS, with Roche Products recommending that larger panel sizes be considered too:

* Australian & New Zealand Society of Cardiac and Thoracic Surgeons;
* Australian Genomics;
* Australian Pathology;
* Clinical Oncology Society of Australia;
* Family Cancer Group;
* Human Genetics Society of Australasia;
* InGeNA;
* Janssen-Cilag;
* Lung Foundation Australia;
* Medical Oncology Group of Australia;
* Breast Cancer Expert Group;
* Private Health Insurance (PHI) branch;
* Public Pathology Australia;
* Roche Products Pty Ltd and Roche Diagnostics Australia; and
* Thoracic Oncology Group Australasia.

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

The Determination commences on 1 November 2023.

Details of the Determination are set out in the Attachment.

Authority: Subsection 3C(1) of the

 *Health Insurance Act 1973*

ATTACHMENT

Details of the *Health Insurance (Section 3C Co-Dependant Pathology) Amendment (No. 2) Determination 2023*

Section 1 – Name

Section 1 provides for the Determination to be referred to as the *Health Insurance (Section 3C Co-Dependant Pathology) Amendment (No. 2) Determination 2023* (the Determination).

Section 2 – Commencement

Section 2 provides for the Determination to commence on 1 November 2023.

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 to co-dependent pathology services

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

**Items 1 to 4** amend the item descriptors of existing co-dependant pathology service items 73337, 73341, 73344 and 73436 to remove mention of specific drugs and classes of drugs. The item descriptors will instead reference ‘an immunotherapy listed under the Pharmaceutical Benefits Scheme (PBS)’. The amended descriptors will also restrict co-claiming with new co‑dependant pathology items (refer to **item 5**).

**Item 5** amends Schedule 1 of the Principal Determination to insert three new co-dependant pathology services:

* New item 73437, which is a nucleic acid-based multi-gene panel testing service using both DNA and RNA techniques to simultaneously test for a minimum of four specified gene variants and a minimum of six specified genes to ascertain fusion status;
* New item 73438, which is a DNA-based multi-gene panel testing service a minimum of four, specified gene variants; and
* New item 73439, which is an RNA-based multi-gene panel testing service of six specified fusion status items.

These new services are to be performed on tumour tissue from a patient with a new diagnosis of non-small cell lung cancer, to determine access to Pharmaceutical Benefits Scheme (PBS) listed immunotherapies.

**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-Dependant Pathology) Amendment (No. 2) Determination 2023***

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 *Health Insurance (Section 3C Co-Dependant Pathology) Amendment (No. 2) Determination 2023* (the Determination) amends the *Health Insurance (Section 3C Co‑Dependent Pathology Services) Determination 2018* (the Principal Determination) from 1 November 2023 to introduce three new pathology items to the Medicare Benefits Scheme (MBS) to streamline testing for genetic variants in patients with non-squamous (or histology not otherwise specified) non‑small cell lung cancer (NSCLC). Minor amendments will also be made to align four existing MBS items for single gene tests for NSCLC with the three new items.

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These new items were recommended by MSAC at its November 2022 meeting under MSAC application 1721.

**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.

*The right of equality and non-discrimination*

The rights of equality and non-discrimination are contained in articles 2, 16 and 26 of the International Covenant on Civil and Political Rights (ICCPR).  Article 26 of the ICCPR requires that all persons are equal before the law, are entitled without any discrimination to the equal protection of the law and in this respect, the law shall prohibit any discrimination and guarantee to all persons equal and effective protection against discrimination on any ground such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.

Analysis

This instrument reflects contemporary clinical practice to ensure that patients have access to safe and effective treatments which support health and social security through relevant subsidised pathology services on the MBS.

**Conclusion**

This instrument is compatible with human rights as it advances the right to health, the right to social security and the right of equality and non-discrimination.

**Mary Warner**

**Assistant Secretary**

**Diagnostic Imaging and Pathology Branch**

**Medicare Benefits and Digital Health Division**

**Health Resourcing Group**

**Department of Health and Aged Care**