

EXPLANATORY STATEMENT

Health Insurance Act 1973

Health Insurance (Pathologist-determinable) Amendment (No. 2) Determination 2023

Section 16A of the *Health Insurance Act 1973* (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 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.

Section 4BA of the Act provides that the Minister for Health may determine by legislative instrument, that a particular pathology service, or pathology services included in a class of pathology services, are pathologist-determinable services after consultation with Royal College of Pathologists of Australasia (RCPA).

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

From 1 November 2023, the *Health Insurance (Section 3C Co-Dependent Pathology Services) Determination 2018* will be amended to list three new pathology items on the Medicare Benefits Schedule (MBS) to test for genetic variants in patients with non-squamous (or histology not otherwise specified) non-small cell lung carcinoma. These three new items will provide specialists and consultant physicians with the opportunity to request Medicare funded, multi-gene panel tests using deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) techniques.

The purpose of the *Health Insurance (Pathologist-determinable) Amendment (No. 2) Determination 2023* (the Amendment Determination) is to amend the *Health Insurance (Pathologist-determinable Services) Determination 2015* (the Principal Determination) from 1 November 2023 to allow three new pathology items (73437, 73438 and 73439) to be performed as a pathologist-determinable service based on the results of a service performed under an item specified under ‘Column 2 Originally requested service’ in the ‘Item 1’ row of the table located in subparagraph 5(b)(iii) of the Principal Determination.

The changes in the Amendment Determination were recommended by the Medical Services Advisory Committee (MSAC) at its November 2022 meeting under *MSAC application 1721 – Small gene panel testing for non-small cell lung carcinoma*.

Consultation

Section 4BA of the Act requires that the RCPA is consulted on any pathology services being made a pathologist-determinable service. The RCPA was the applicant for MSAC application 1721 and was consulted throughout the MSAC process.

Details of the Amendment Determination are set out in the Attachment.

The Amendment Determination commences on 1 November 2023.

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

Authority: Section 4BA of the
Health Insurance Act 1973

Details of the *Health Insurance (Pathologist-determinable) Amendment (No. 2) Determination 2023*

Section 1 – Name

Section 1 provides for the Amendment Determination to be referred to as the *Health Insurance (Pathologist-determinable) Amendment (No. 2) Determination 2023* (Amendment Determination)

Section 2 – Commencement

Section 2 provides that the Amendment Determination commences 1 November 2023.

Section 3 – Authority

Section 3 provides that the Amendment Determination is made under section 4BA of the *Health Insurance Act 1973*.

Section 4 – Schedules

Section 4 provides that each instrument that is specified in a Schedule to this Amendment 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 Amendment Determination has effect according to its terms.

Schedule 1 – Amendments

Health Insurance (Pathologist-determinable Services) Determination 2015

Item 1 inserts pathology items 73437, 73438 and 73439 into subparagraph 5(b)(iii), allowing the items to be performed where an approved pathology practitioner deems the service to be necessary following testing under an item specified under ‘Column 2 Originally requested service’ in the “Item 1” row of the table located in subparagraph 5(b)(iii) of the *Health Insurance (Pathologist-determinable Services) Determination 2015*. Under this change, patients who are undergoing testing under MBS items 72813, 72816, 72817, 72818, 72823, 72824, 72825, 72826, 72827, 72828, 72830, 72836 and/or 72838 may also receive a service under items 73437, 73438 and/or 73439 if the pathologist deems it as a necessary service to test for genetic variants in patients with non-squamous (or histology not otherwise specified) non-small cell lung cancer.

Statement of Compatibility with Human Rights

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

Health Insurance (Pathologist-determinable) 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

From 1 November 2023, the *Health Insurance (Section 3C Co-Dependent Pathology Services) Determination 2018* will be amended to list three new pathology items on the Medicare Benefits Schedule (MBS) to test for genetic variants in patients with non-squamous (or histology not otherwise specified) non-small cell lung carcinoma. These three new items will provide specialists and consultant physicians with the opportunity to request Medicare funded, multi-gene panel tests using deoxyribonucleic acid (DNA) and ribonucleic acid (RNA) techniques.

The purpose of the *Health Insurance (Pathologist-determinable) Amendment (No. 2) Determination 2023* (the Amendment Determination) is to amend the *Health Insurance (Pathologist-determinable Services) Determination 2015* (the Principal Determination) from 1 November 2023 to allow three new pathology items (73437, 73438 and 73439) to be performed as a pathologist-determinable service based on the results of a service performed under an item specified under ‘Column 2 Originally requested service’ in the “Item 1” row of the table located in subparagraph 5(b)(iii) of the Principal Determination.

The changes in the Amendment Determination were recommended by the Medical Services Advisory Committee (MSAC) at its November 2022 meeting under *MSAC application 1721 – Small gene panel testing for non-small cell lung carcinoma*.

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 maintains the right to health, the right to social security and the right of equality and non-discrimination by providing specialists and consultant physicians with access to Medicare support when ordering tests for genetic variants in patients with non-squamous (or histology not otherwise specified) non-small cell lung carcinoma.

This instrument will continue to support access to Medicare benefits for patients requiring small gene panel testing for non-small cell lung cancer.

Conclusion

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

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