EXPLANATORY STATEMENT

Health Insurance Act 1973

Health Insurance (Pathologist-determinable Services) Amendment (No. 2) Determination 2022

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

The purpose of the *Health Insurance (Pathologist-determinable Services) Amendment (No. 2) Determination 2022* (the Amendment Determination) is to amend the *Health Insurance (Pathologist-determinable Services) Determination 2015* (the Principal Determination) from 1 November 2022. The Amendment Determination will allow new item 73436 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 new item (73436), which will be created in the *Health Insurance (Section 3C Co-Dependent Pathology Services) Amendment Determination (No. 6) 2022*, will provide Medicare funding for MET proto-oncogene, receptor tyrosine kinase (MET) exon 14 skipping alterations (*METex14sk*) testing in patients diagnosed with locally advanced or metastatic non-small cell lung cancer (NSCLC) to determine eligibility for treatment with tepotinib under the Pharmaceutical Benefits Scheme (PBS). *METex14sk* is a specific type of genetic variation that can result in faster tumour growth and patients with *METex14sk* commonly have a worse prognosis than those without these alterations. Tepotinib is a targeted drug that can improve health outcomes in patients who have *METex14sk*.

For the selection of therapies for treatment of advanced NSCLC, current clinical guidelines recommend performing sequential biomarker testing prior to the initiation of treatment.

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The addition of item 73436 as a Pathologist-determinable Service will allow patients diagnosed with locally advanced or metastatic NSCLC who are undergoing sequential biomarker testing to have access to a clinically appropriate Medicare funded *METex14sk* test, as determined by an expert pathologist, without the need to return to a treating practitioner to arrange another pathology request for a *METex14sk* test. This will prevent potential delays for relevant cancer patients. The RCPA supports this amendment in the interest of patients.

At its March 2022 meeting, the Pharmaceutical Benefits Advisory Committee (PBAC) recommended the PBS listing of tepotinib for the treatment of patients diagnosed with local advanced or metastatic MET exon 14 skipping alterations-positive NSCLC. The Medical Services Advisory Committee (MSAC) had previously supported the creation of a new Medicare Benefits Schedule (MBS) item for *METex14sk* testing in patients diagnosed with locally advanced or metastatic NSCLC to determine eligibility for tepotinib under the PBS at its November 2021 meeting.

Consultation
Section 4BA of the Act requires that the RCPA is consulted on pathology services being made a pathologist-determinable service. The RCPA was consulted on the inclusion of item 73436 and support the item being made pathologist-determinable service.

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

The Amendment Determination commences on 1 November 2022.

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

Authority: Section 4BA of the *Health Insurance Act 1973*

ATTACHMENT

Details of the *Health Insurance (Pathologist-determinable Services) Amendment (No. 2) Determination 2022*

Section 1 – Name

Section 1 provides for the Amendment Determination to be referred to as the *Health Insurance (Pathologist-determinable Services) Amendment (No. 2) Determination 2022*.

Section 2 – Commencement

Section 2 provides that the Amendment Determination commences on 1 November 2022.

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

Amendment item 1 inserts pathology item 73436 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*. The addition of item 73436 as a Pathologist-determinable Service will allow patients diagnosed with locally advanced or metastatic NSCLC who are undergoing sequential biomarker testing to have access to a clinically appropriate Medicare funded *METex14sk* test, as determined by an expert pathologist, without the need to return to a treating practitioner to arrange another pathology request.

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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 (No. 2) Determination 2022

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 (No. 2) Determination 2022* (the Amendment Determination) is to amend the *Health Insurance (Pathologist-determinable Services) Determination 2015* (the Principal Determination) from 1 November 2022. The Amendment Determination will allow new item 73436 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 new item (73436), which will be created in the *Health Insurance (Section 3C Co-Dependent Pathology Services) Amendment Determination (No. 6) 2022*, will provide Medicare funding for MET proto-oncogene, receptor tyrosine kinase (MET) exon 14 skipping alterations (*METex14sk*) testing in patients diagnosed with locally advanced or metastatic non-small cell lung cancer (NSCLC) to determine eligibility for treatment with tepotinib under the Pharmaceutical Benefits Scheme (PBS). *METex14sk* is a specific type of genetic variation that can result in faster tumour growth and patients with *METex14sk* commonly have a worse prognosis than those without these alterations. Tepotinib is a targeted drug that can improve health outcomes in patients who have *METex14sk*.

For the selection of therapies for treatment of advanced NSCLC, current clinical guidelines recommend performing sequential biomarker testing prior to the initiation of treatment. The addition of item 73436 as a Pathologist-determinable Service will allow patients diagnosed with locally advanced or metastatic NSCLC who are undergoing sequential biomarker testing to have access to a clinically appropriate Medicare funded *METex14sk* test, as determined by an expert pathologist, without the need to return to a treating practitioner to arrange another pathology request for a *METex14sk* test. This will prevent potential delays for relevant cancer patients. The RCPA supports this amendment in the interest of patients.

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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.

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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 patients diagnosed with locally advanced or metastatic NSCLC who are undergoing sequential biomarker testing to have access to a clinically appropriate Medicare funded *METex14sk* test, as determined by an expert pathologist, without the need to return to a treating practitioner to arrange another pathology request for a METex14sk test.

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Conclusion

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

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