

EXPLANATORY STATEMENT

Health Insurance Act 1973

Health Insurance (Section 3C Co-Dependent Pathology Services) Amendment (No. 1) Determination 2025

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

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 (Section 3C Co-Dependent Pathology Services) Amendment (No. 1) Determination 2025* (the Amendment Determination) is to amend the *Health Insurance (Section 3C Co-Dependent Pathology Services) Determination 2018* (the Principal Determination) from 1 November 2025.

From 1 November 2025, item 66520 for fibroblast growth factor 23 (FGF-23) testing will be introduced to Group P2 of the Medicare Benefits Schedule (MBS). Item 66520 will provide for FGF-23 testing for patients with a high pre-test probability of X-linked hypophosphatemia (XLH) to determine eligibility for a relevant treatment listed on the Pharmaceutical Benefits Scheme (PBS). Burosumab is a relevant treatment for XLH and is listed on the PBS. However, the descriptor for the new item 66520 refers to a relevant treatment listed on the PBS, rather than burosumab, to allow item 66520 to be used to determine eligibility for treatments that may be listed on the PBS in future.

Additionally, the Amendment Determination will amend the Principal Determination to make non-small cell lung cancer (NSCLC) items 73337, 73341, 73344, and 73436 consistent with items 73437 to 73439. Amendments will be made to items 73341, 73344 and 73436 to allow patients access to immunohistochemistry (IHC) and fluorescence in situ hybridisation (FISH) testing at any diagnostic stage of NSCLC, where pathology laboratories do not yet have Next Generation Sequencing (NGS) technology - this is in line with the latest advice from the Medical Services Advisory Committee (MSAC) for the NSCLC patient population.

The descriptors for items 73337, 73341 and 73344 will be amended to align them with the descriptors for items 73436 to 73439 by removing the reference to cancer that is of non-squamous histology or histology not otherwise specified. The

descriptors for items 73341 and 73344 will also be amended to remove references to previous biomarker tests and results. Additionally, items 73337, 73341, 73344, 73436 and 73437 to 73439 will be amended to refer to relevant PBS treatments, rather than an immunotherapy listed under the PBS, in accordance with MSAC's preferred language for co-dependent pathology item descriptors.

The changes in the Amendment Determination were agreed to by the Minister for Health and Ageing through the Minister's authority to approve certain MSAC recommendations outside of a budget process.

Consultation

Consultation was undertaken on the introduction of new MBS item 66520. Australian Pathology (AP), Public Pathology Australia (PPA) and the Hypophosphatemic Working Party of the Australian and New Zealand Bone and Mineral Society provided feedback on the relevance of the service and the MBS schedule fee and were supportive of the listing of the new item.

The Royal College of Pathologists of Australasia, AP and PPA were consulted on the proposed item descriptor changes to the NSCLC items described above, and did not raise any concerns.

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

The Amendment Determination commences on 1 November 2025.

Details of the Amendment 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-Dependent Pathology Services) Amendment (No. 1) Determination 2025*Section 1 – Name

Section 1 provides for the Amendment Determination to be referred to as the *Health Insurance (Section 3C Co-Dependent Pathology Services) Amendment (No. 1) Determination 2025* (the Amendment Determination).

Section 2 – Commencement

Section 2 provides for the Amendment Determination to commence on 1 November 2025.

Section 3 – Authority

Section 3 provides that the Amendment 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 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 (Section 3C Co-Dependent Pathology Services) Determination 2018 (the Principal Determination)

Item 1 amends paragraph 6(1)(b) of the Principal Determination to add reference to Group P2 to the paragraph. Section 6 of the Principal Determination provides general application rules for services included in Schedule 1 and outlines how relevant services are to be treated under the *Health Insurance Act 1973*. As a result, a service provided under new Medicare Benefits Schedule (MBS) item 66520 (see **amendment item 2**) will be treated as if there were an item in Group P2 of the Pathology Services Table that related to the service and specified a fee in relation to the service.

Item 2 introduces new MBS item 66520 for fibroblast growth factor 23 (FGF-23) quantification requested by a specialist or consultant physician to determine eligibility for a relevant treatment listed on the Pharmaceutical Benefits Scheme (PBS) from 1 November 2025. **Amendment item 2** also adds Group P2 to the Principal Determination, as item 66520 will be introduced into Group P2 of the MBS.

Item 3 amends MBS item 73337 to remove the reference to a non-small cell lung cancer with non-squamous histology or histology not otherwise specified, to align with item 73436 and the newest NSCLC items 73437 to 73439.

Items 4 to 14 (except items 5, 7 and 9) amend MBS items 73337, 73341, 73344, 73436, 73437, 73438 and 73439 to reflect the Medical Services Advisory Committee's preferred phrasing for co-dependent pathology item descriptors to refer to relevant treatments under the PBS, rather than an immunotherapy listed under the PBS.

Items 5 and 7 amend MBS items 73341 and 73344, respectively, to remove references to previous biomarker tests and results, as this information is included in the PBS restrictions and is not required in the MBS item descriptor. The items also amend MBS items 73341 and 73344 to remove the requirement that the non-small lung cancer referred to in these items be locally advanced or metastatic, enabling access to immunohistochemistry (IHC) and fluorescence in situ hybridisation (FISH) testing at any diagnostic stage where pathology laboratories do not yet have Next Generation Sequencing (NGS) technology. Additionally, as with item 3 above, items 3 and 5 amend MBS items 73341 and 73344 to remove the reference to a non-small lung cancer with non-squamous histology or histology not otherwise specified.

Item 9 amends MBS item 73436 to remove the requirement that the non-small cell lung cancer referred to in this item be locally advanced or metastatic, enabling access to IHC and FISH testing at any diagnostic stage where pathology laboratories do not yet have NGS technology.

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 (No. 1) Determination 2025

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 (No. 1) Determination 2025* (the Amendment Determination) is to amend the *Health Insurance (Section 3C Co-Dependent Pathology Services) Determination 2018* (the Principal Determination) from 1 November 2025.

From 1 November 2025, item 66520 for fibroblast growth factor 23 (FGF-23) testing will be introduced to Group P2 of the Medicare Benefits Schedule (MBS). Item 66520 will provide for FGF-23 testing for patients with a high pre-test probability of X-linked hypophosphatemia (XLH) to determine eligibility for a relevant treatment listed on the Pharmaceutical Benefits Scheme (PBS). Burosumab is a relevant treatment for XLH and is listed on the PBS. However, the descriptor for the new item 66520 refers to a relevant treatment listed on the PBS, rather than burosumab, to allow item 66520 to be used to determine eligibility for treatments that may be listed on the PBS in future.

Additionally, the Amendment Determination will amend the Principal Determination to make non-small cell lung cancer (NSCLC) items 73337, 73341, 73344, and 73436 consistent with items 73437 to 73439. Amendments will be made to items 73341, 73344 and 73436 to allow patients access to immunohistochemistry (IHC) and fluorescence in situ hybridisation (FISH) testing at any diagnostic stage of NSCLC, where pathology laboratories do not yet have Next Generation Sequencing (NGS) technology - this is in line with the latest advice from the Medical Services Advisory Committee (MSAC) for the NSCLC patient population.

The descriptors for items 73337, 73341 and 73344 will be amended to align them with the descriptors for items 73436 to 73439 by removing the reference to cancer that is of non-squamous histology or histology not otherwise specified. The descriptors for items 73341 and 73344 will also be amended to remove references to previous biomarker tests and results. Additionally, items 73337, 73341, 73344, 73436 and 73437 to 73439 will be amended to refer to relevant PBS treatments, rather than an immunotherapy listed under the PBS, in accordance with MSAC's preferred language for co-dependent pathology item descriptors.

The changes in the Amendment Determination were agreed to by the Minister for Health and Ageing through the Minister's authority to approve certain MSAC recommendations outside of a budget process.

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

The Amendment Determination will reflect contemporary clinical practice by expanding patient access to IHC and FISH testing at any diagnostic stage of NSCLC and streamlining descriptors for NSCLC items, and by enabling patients with a high pre-test probability of XLH to access a MBS-funded test for to determine eligibility for a relevant treatment listed on the PBS. This is to ensure that patients continue to have access to health and social security through relevant subsidised diagnostic imaging services on the MBS.

Conclusion

This instrument is compatible with human rights as it maintains the right to health and the right to social security and the right of equality and non-discrimination. New MBS item 66520 will allow patients to access MBS benefits when determining eligibility for medicines listed on the PBS.

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