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

I, Mary Warner, delegate of the Minister for Health and Ageing, make the following Determination.

Dated 26 August 2025

Mary Warner
Assistant Secretary
Diagnostic Imaging and Pathology Branch
Medicare Benefits and Digital Health Division
Health Resourcing Group
Department of Health, Disability and Ageing

Contents

1 Name

This instrument is the *Health Insurance (Section 3C Co-Dependent Pathology Services) Amendment (No. 1) Determination 2025*.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	**Column 2**	**Column 3**
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument	1 November 2025.	1 November 2025

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under subsection 3C(1) of the *Health Insurance Act 1973*.

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

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

1 Paragraph 6(1)(b)

Omit "P5 or P7", substitute "P2, P5 or P7".

2 Table at Schedule 1 (at the beginning of the table)

Insert:

Group P2—Chemical		
Item	**Description**	**Fee ($)**
66520	Fibroblast growth factor 23 quantification in serum or plasma, requested by a specialist or consultant physician to determine eligibility for a relevant treatment listed on the Pharmaceutical Benefits Scheme	90.00

3 Schedule 1 (item 73337, column 2)

Omit "shown to have non-squamous histology or histology not otherwise specified, ".

4 Schedule 1 (item 73337, column 2, paragraph (a))

Repeal the paragraph, substitute:

(a) for epidermal growth factor receptor (EGFR) status to determine eligibility for a relevant treatment under the Pharmaceutical Benefits Scheme; and

5 Schedule 1 (item 73341, column 2)

Omit "locally advanced or metastatic non-small cell lung cancer, which is of non-squamous histology or histology not otherwise specified, with documented evidence of anaplastic lymphoma kinase (ALK) immunoreactivity by immunohistochemical (IHC) examination giving a staining intensity score > 0, and with documented absence of activating mutations of the epidermal growth factor receptor (EGFR) gene,", substitute "non-small cell lung cancer,".

6 Schedule 1 (item 73341, column 2, paragraph (a))

Repeal the paragraph, substitute:

(a) for ALK gene rearrangement status to determine eligibility for a relevant treatment under the Pharmaceutical Benefits Scheme; and

7 Schedule 1 (item 73344, column 2)

Omit “locally advanced or metastatic non-small cell lung cancer, which is of non-squamous histology or histology not otherwise specified, with documented evidence of ROS proto-oncogene 1 (ROS1) immunoreactivity by immunohistochemical (IHC) examination giving a staining intensity score of 2+ or 3+; and with documented absence of both activating mutations of the epidermal growth factor receptor (EGFR) gene and anaplastic lymphoma kinase (ALK) immunoreactivity by IHC,”, substitute “non-small cell lung cancer,”.

8 Schedule 1 (item 73344, column 2, paragraph (a))

Repeal the paragraph, substitute:

(a) for ROS1 gene arrangement status to determine eligibility for a relevant treatment under the Pharmaceutical Benefits Scheme; and

9 Schedule 1 (item 73436, column 2)

Omit “locally advanced or metastatic ”.

10 Schedule 1 (item 73436, column 2, paragraph (a))

Repeal the paragraph, substitute:

(a) for MET proto-oncogene, receptor tyrosine kinase (MET) exon 14 skipping alterations (METex14sk) status to determine eligibility for access to a relevant treatment under the Pharmaceutical Benefits Scheme; and.

11 Schedule 1 (item 73437, column 2, paragraph (a))

Omit “access to specific therapies relevant to these variants listed on the Pharmaceutical Benefits Scheme (PBS);”, substitute “eligibility for a relevant treatment under the Pharmaceutical Benefits Scheme;”.

12 Schedule 1 (item 73437, column 2, paragraph (b))

Repeal the paragraph, substitute:

(b) to detect the fusion status of at least ALK, ROS1, RET, NTRK1, NTRK2 and NTRK3 to determine eligibility for a relevant treatment under the PBS; and

13 Schedule 1 (item 73438, column 2, paragraph (b), (c) and (d))

Repeal the paragraphs, substitute:

(b) to determine eligibility for a relevant treatment under the Pharmaceutical Benefits Scheme; and

(c) not associated with a service to which item 73437, 73337, 73436 or 73351 applies

14 Schedule 1 (item 73439, column 2, paragraph (a), (b) and (c))

Repeal the paragraphs, substitute:

(a) for fusion status of at least ALK, ROS1, RET, NTRK1, NTRK2, and NTRK3 to determine eligibility for a relevant treatment under the Pharmaceutical Benefits Scheme; and

(b) not associated with a service to which item 73437, 73341, 73344 or 73351 applies