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

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

Dated 20 September 2023

Mary Warner
Assistant Secretary
Diagnostic Imaging and Pathology Branch
Medicare Benefits and Digital Health Division
Health Resourcing Group
Department of Health and Aged Care

Contents

1 Name

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

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 2023.	

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 to co-dependent pathology services

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

1 Schedule 1 (cell at item 73337, column 2)

Repeal the cell, substitute:

A test of tumour tissue from a patient with a new diagnosis of non-small cell lung cancer, shown to have non-squamous histology or histology not otherwise specified, requested by, or on behalf of, a specialist or consultant physician, if the test is:

(a) to determine if requirements relating to epidermal growth factor receptor (EGFR) gene status for access to an immunotherapy listed under the Pharmaceutical Benefits Scheme (PBS) are fulfilled; and

(b) not associated with a service to which item 73437 or 73438 applies

2 Schedule 1 (cell at item 73341, column 2)

Repeal the cell, substitute:

Fluorescence in situ hybridisation (FISH) test of tumour tissue from a patient with a new diagnosis of 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, requested by a specialist or consultant physician, if the test is:

(a) to determine if requirements relating to ALK gene rearrangement status for access to an immunotherapy listed under the Pharmaceutical Benefits Scheme (PBS) are fulfilled; and

(b) not associated with a service to which item 73437 or 73439 applies

3 Schedule 1 (cell at item 73344, column 2)

Repeal the cell, substitute:

Fluorescence in situ hybridization (FISH) test of tumour tissue from a patient with a new diagnosis of 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, requested by a specialist or consultant physician, if the test is:

(a) to determine if requirements relating to ROS1 gene arrangement status for access to an immunotherapy listed under the Pharmaceutical Benefits Scheme (PBS) are fulfilled: and

(b) not associated with a service to which item 73437 or 73439 applies

4 Schedule 1 (cell at item 73436, column 2)

Repeal the cell, substitute:

A test of tumour tissue from a patient with a new diagnosis of locally advanced or metastatic non-small cell lung cancer requested by, or on behalf of, a specialist or consultant physician, if the test is:

(a) to determine if the requirements relating to MET proto-oncogene, receptor tyrosine kinase (MET) exon 14 skipping alterations (METex14sk) status for access to an immunotherapy listed under the Pharmaceutical Benefits Scheme (PBS) are fulfilled: and

(b) not associated with a service to which item 73437 or 73438 applies

5 Schedule 1 (after item 73436)

Add:

73437	A nucleic acid-based multi-gene panel test of tumour tissue from a patient with a new diagnosis of non-small cell lung cancer requested by, or on behalf of, a specialist or consultant physician, if the test is: (a) to detect variants in at least EGFR, BRAF, KRAS and MET exon 14 to determine access to specific therapies relevant to these variants listed on the Pharmaceutical Benefits Scheme (PBS); and (b) to detect the fusion status of at least ALK, ROS1, RET, NTRK1, NTRK2 and NTRK3; and (i) to determine access to specific therapies relevant to these variants listed on the PBS; or (ii) determine if the requirements relating to EGFR, ALK and ROS1 status for access immunotherapies listed on the PBS are fulfilled; and (c) not associated with a service to which item 73438, 73439, 73337, 73341, 73344, 73436 or 73351 applies	1,247.00
73438	A DNA-based multi-gene panel test of tumour tissue from a patient with a new diagnosis of non-small cell lung cancer requested by, or on behalf of, a specialist or consultant physician, if the test is: (a) to detect variants in at least EGFR, BRAF, KRAS and MET exon 14; and (b) to determine access to specific therapies relevant to these variants listed on the Pharmaceutical Benefits Scheme (PBS); or (c) to determine if the requirements relating to EGFR status for access to immunotherapies listed on the PBS are fulfilled; and (d) not associated with a service to which item 73437, 73337, 73436 or 73351 applies	682.35

73439	A nucleic acid-based multi-gene panel test of tumour tissue from a patient with a new diagnosis of non-small cell lung cancer and with documented absence of activating variants of the EGFR gene, KRAS, BRAF and MET exon14, requested by, or on behalf of, a specialist or consultant physician, if the test is: (a) to determine the fusion status of at least ALK, ROS1, RET, NTRK1, NTRK2, and NTRK3 to determine access to specific therapies relevant to these variants listed on the Pharmaceutical Benefits Scheme (PBS) are fulfilled; or (b) to determine if the requirements relating to ALK and ROS1 status for access to immunotherapies listed on the PBS are fulfilled; and (c) not associated with a service to which item 73437, 73341, 73344 or 73351 applies	682.35