



Health Insurance (Section 3C Co-Dependent Pathology Services) Amendment Determination 2021

I, Travis Haslam, delegate of the Minister for Health and Aged Care, make the following Determination.

Dated 14 September 2021

Travis Haslam
Acting First Assistant Secretary
Medical Benefits Division
Health Resourcing Group
Department of Health

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1 Name

This instrument is the *Health Insurance (Section 3C Co-Dependent Pathology Services) Amendment Determination 2021*.

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 2021	

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 Schedule 1 (cell at item 72814, column 2)

Repeal the cell, substitute:

Immunohistochemical examination by immunoperoxidase or other labelled antibody techniques using the programmed cell death ligand 1 (PD-L1) antibody of tumour material from a patient diagnosed with non-small cell lung cancer.

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

Repeal the cell, substitute:

A test of tumour tissue from a patient diagnosed with 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, to determine:

- (a) if the requirements relating to epidermal growth factor receptor (EGFR) gene status for access to an EGFR tyrosine kinase inhibitor under the Pharmaceutical Benefits Scheme are fulfilled; or
- (b) if the requirements relating to EGFR status for access to pembrolizumab under the Pharmaceutical Benefits Scheme are fulfilled.

3 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 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, to determine:

- (a) if requirements relating to ALK gene rearrangement status for access to an anaplastic lymphoma kinase inhibitor under the Pharmaceutical Benefits Scheme are fulfilled; or
- (b) if requirements relating to ALK status for access to pembrolizumab under the Pharmaceutical Benefits Scheme are fulfilled.

4 Schedule 1 (item 73343)

Repeal the item, substitute:

73343 Detection of 17p chromosomal deletions by fluorescence in situ hybridisation or genome wide micro-array, in a patient with relapsed or refractory chronic lymphocytic leukaemia or small lymphocytic lymphoma, on a peripheral blood or bone marrow sample, requested by a specialist or consultant physician, to determine if the requirements for access to idelalisib, ibrutinib, venetoclax or acalabrutinib on the Pharmaceutical Benefits Scheme are fulfilled. 589.90

For any particular patient, applicable not more than once in 12 months.

5 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 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, to determine:

- (a) if requirements relating to ROS1 gene arrangement status for access to crizotinib or entrectinib under the Pharmaceutical Benefits Scheme are fulfilled; or
- (b) if requirements relating to ROS1 status for access to pembrolizumab under the Pharmaceutical Benefits Scheme are fulfilled.