



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

I, Celia Street, delegate of the Minister for Health, make this Determination under subsection 3C(1) of the *Health Insurance Act 1973*.

Dated            19 June 2018

Celia Street  
Assistant Secretary  
Diagnostic Imaging and Pathology Branch  
Medical Benefits Division  
Department of Health

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**1. Name of Determination**

This Determination is the *Health Insurance (Section 3C Co-Dependent Pathology Services) Determination 2018*.

**2. Commencement**

This Determination commences immediately after the commencement of the *Health Insurance (Pathology Services Table) Regulations 2018*.

**3. Authority**

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

**4. Revokes**

This Determination revokes the following instruments:

- (a) the [\*Health Insurance \(Pharmacogenetic Testing – Human Epidermal Growth Factor Receptor 2\) Determination 2015\*](#)
- (b) the [\*Health Insurance \(ALK Gene Testing\) Determination 2017\*](#)
- (c) the [\*Health Insurance \(Section 3C Pathology Services—BRAF Gene Testing\) Determination 2017\*](#)
- (d) the [\*Health Insurance \(Section 3C Pathology Services – BRCA Gene Testing No.2\) Determination 2017\*](#)
- (e) the [\*Health Insurance \(Section 3C Pathology Services—17p Deletion Testing\) Determination 2017\*](#)

**5. Definitions**

- (1) In this Determination:

**Act** means the *Health Insurance Act 1973*.

**relevant provisions** means all provisions, of the Act and regulations made under the Act, and the *National Health Act 1953* and regulations made under the *National Health Act 1953*, relating to medical services, professional services or items.

**relevant service** means a health service, as defined in subsection 3C(8) of the Act, that is specified in a Schedule.

**Pathology services table** means the table prescribed under subsection 4A(1) of the Act.

**Pharmaceutical Benefits Scheme** means the scheme for the supply of pharmaceutical benefits established under Part VII of the *National Health Act 1953*.

**Schedule** means a Schedule to this Determination.

Note: The following terms are defined in subsection 3(1) of the Act:

- clinically relevant service
- pathology services table
- item
- professional service

- (2) Unless the contrary intention appears, a reference in this Determination to a provision of the Act or the *National Health Act 1953* or regulations made under the Act or under the *National Health Act 1953* as applied, adopted or incorporated in relation to specifying a matter is a reference to those provisions as in force from time to time and any other reference to provisions of an Act or regulations is a reference to those provisions as in force from time to time.

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**6. Treatment of relevant services**

- (1) For subsection 3C(1) of the Act a relevant service, provided in accordance with this Determination and as a clinically relevant service, is to be treated, for the relevant provisions, as if:
- (a) it were both a professional service and a pathology service; and
  - (b) there were an item in Group P7 of the pathology services table that:
    - (i) related to the service; and
    - (ii) specified for the service a fee in relation to each State, being the fee specified in Schedule 1 in relation to the service.

## Schedule 1 – Relevant Services

<b>Group P7—Genetics</b>		
<b>Item</b>	<b>Description</b>	<b>Fee (\$)</b>
73295	Detection of germline BRCA1 or BRCA2 gene mutations, in a patient with platinum-sensitive relapsed ovarian, fallopian tube or primary peritoneal cancer with high grade serous features or a high grade serous component, and who has responded to subsequent platinum-based chemotherapy, requested by a specialist or consultant physician, to determine whether the eligibility criteria for olaparib under the Pharmaceutical Benefits Scheme are fulfilled.	1,200.00
	Maximum of one test per patient's lifetime	
73332	An in situ hybridisation (ISH) test of tumour tissue from a patient with breast cancer requested by, or on the advice of, a specialist or consultant physician who manages the treatment of the patient to determine if the requirements relating to human epidermal growth factor receptor 2 (HER2) gene amplification for access to trastuzumab under the Pharmaceutical Benefits Scheme or the Herceptin Program are fulfilled.	315.40
73336	A test of tumour tissue from a patient with unresectable stage III or stage IV metastatic cutaneous melanoma, requested by, or on behalf of, a specialist or consultant physician, to determine if the requirements relating to BRAF V600 mutation status for access to dabrafenib or vemurafenib under the Pharmaceutical Benefits Scheme are fulfilled	230.95
73337	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 if the requirements relating to epidermal growth factor receptor (EGFR) gene status for access to erlotinib, gefitinib or afatinib under the Pharmaceutical Benefits Scheme are fulfilled	397.35
73338	A test of tumour tissue from a patient with metastatic colorectal cancer (stage IV), requested by a specialist or consultant physician, to determine if the requirements relating to rat sarcoma oncogene (RAS) gene mutation status for access to cetuximab or panitumumab under the Pharmaceutical Benefits Scheme are fulfilled, if:  (a) the test is conducted for all clinically relevant mutations on KRAS exons 2, 3 and 4 and NRAS exons 2, 3, and 4; or  (b) a RAS mutation is found.	362.60
73341	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 if requirements relating to ALK gene rearrangement status for access to crizotinib, ceritinib or alectinib under the Pharmaceutical Benefits Scheme are fulfilled.	400.00

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**Group P7—Genetics**

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<b>Item</b>	<b>Description</b>	<b>Fee (\$)</b>
73342	An in situ hybridisation (ISH) test of tumour tissue from a patient with metastatic adenocarcinoma of the stomach or gastro-oesophageal junction, with documented evidence of human epidermal growth factor receptor 2 (HER2) overexpression by immunohistochemical (IHC) examination giving a staining intensity score of 2+ or 3+ on the same tumour tissue sample, requested by, or on the advice of, a specialist or consultant physician who manages the treatment of the patient to determine if the requirements relating to HER2 gene amplification for access to trastuzumab under the Pharmaceutical Benefits Scheme are fulfilled.	315.40
73343	Detection of 17p chromosomal deletions by fluorescence in situ hybridisation, 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 or ibrutinib under the Pharmaceutical Benefits Scheme are fulfilled.	230.95