

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

made under subsection 3C(1) of the

Health Insurance Act 1973

**Compilation No. 11**

**Compilation date:** 1 November 2021

**Includes amendments up to:** F2021L01270

**Registered:** 11 November 2021

**About this compilation**

**This compilation**

This is a compilation of the *Health Insurance (Section 3C Co-Dependent Pathology Services) Determination 2018* that shows the text of the law as amended and in force on 1 November 2021 (the ***compilation date***).

The notes at the end of this compilation (the ***endnotes***) include information about amending laws and the amendment history of provisions of the compiled law.

**Uncommenced amendments**

The effect of uncommenced amendments is not shown in the text of the compiled law. Any uncommenced amendments affecting the law are accessible on the Legislation Register (www.legislation.gov.au). The details of amendments made up to, but not commenced at, the compilation date are underlined in the endnotes. For more information on any uncommenced amendments, see the series page on the Legislation Register for the compiled law.

**Application, saving and transitional provisions for provisions and amendments**

If the operation of a provision or amendment of the compiled law is affected by an application, saving or transitional provision that is not included in this compilation, details are included in the endnotes.

**Editorial changes**

For more information about any editorial changes made in this compilation, see the endnotes.

**Modifications**

If the compiled law is modified by another law, the compiled law operates as modified but the modification does not amend the text of the law. Accordingly, this compilation does not show the text of the compiled law as modified. For more information on any modifications, see the series page on the Legislation Register for the compiled law.

**Self‑repealing provisions**

If a provision of the compiled law has been repealed in accordance with a provision of the law, details are included in the endnotes.

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# 1. Name of Determination

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

# 3. Authority

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

# 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.

# 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 Groups P5 or 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

| **Group P5—Tissue pathology** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Item** | | **Description** | **Fee ($)** | | |
| 72814 | 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. | | | 74.50 |

| **Group P7—Genetics** | | | |
| --- | --- | --- | --- |
| **Item** | **Description** | **Fee ($)** | |
| 73295 | Detection of germline *BRCA1* or *BRCA2* pathogenic or likely pathogenic gene variants, in a patient with advanced (FIGO III-IV) high-grade serous or high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer for whom testing of tumour tissue is not feasible, requested by a specialist or consultant physician, to determine eligibility for olaparib under the Pharmaceutical Benefits Scheme (PBS)  Maximum of one test per patient’s lifetime | | 1,200.00 |
| 73301 | A test of tumour tissue from a patient with advanced (FIGO III-IV), high grade serous or high grade epithelial ovarian, fallopian tube or primary peritoneal cancer, requested by a specialist or consultant physician, to determine eligibility relating to *BRCA* status for access to olaparib under the Pharmaceutical Benefits Scheme (PBS)  Applicable once per primary tumour diagnosis | | 1,200.00 |
| 73302 | Characterisation of germline gene variants including copy number variants, in *BRCA1* or *BRCA2* genes, in a patient who has had a pathogenic or likely pathogenic variant identified in either gene by tumour testing and who has not previously received a service to which items 73295, 73296 or 73297 applies, requested by a specialist or consultant physician  Applicable once per primary tumour diagnosis  Note: Items 73296 and 73297 are in the pathology services table. | | 400.00 |
| 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 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, vemurafenib or encorafenib 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:  (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. | | 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:  (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. | | 400.00 |
| 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 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.  For any particular patient, applicable not more than once in 12 months. | | 589.90 |
| 73344 | 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. | | 400.00 |
| 73351 | A test of tumour tissue that is derived from a new sample from a patient with locally advanced (Stage IIIb) or metastatic (Stage IV) non‑small cell lung cancer (NSCLC), who has progressed on or after treatment with an epidermal growth factor receptor tyrosine kinase inhibitor (EGFR TKI). The test is to be requested by a specialist or consultant physician, to determine if the requirements relating to *EGFR* *T790M* gene status for access to osimertinib under the Pharmaceutical Benefits Scheme are fulfilled. | | 397.35 |

Endnotes

Endnote 1—About the endnotes

The endnotes provide information about this compilation and the compiled law.

The following endnotes are included in every compilation:

Endnote 1—About the endnotes

Endnote 2—Abbreviation key

Endnote 3—Legislation history

Endnote 4—Amendment history

**Abbreviation key—Endnote 2**

The abbreviation key sets out abbreviations that may be used in the endnotes.

**Legislation history and amendment history—Endnotes 3 and 4**

Amending laws are annotated in the legislation history and amendment history.

The legislation history in endnote 3 provides information about each law that has amended (or will amend) the compiled law. The information includes commencement details for amending laws and details of any application, saving or transitional provisions that are not included in this compilation.

The amendment history in endnote 4 provides information about amendments at the provision (generally section or equivalent) level. It also includes information about any provision of the compiled law that has been repealed in accordance with a provision of the law.

**Editorial changes**

The *Legislation Act 2003* authorises First Parliamentary Counsel to make editorial and presentational changes to a compiled law in preparing a compilation of the law for registration. The changes must not change the effect of the law. Editorial changes take effect from the compilation registration date.

If the compilation includes editorial changes, the endnotes include a brief outline of the changes in general terms. Full details of any changes can be obtained from the Office of Parliamentary Counsel.

**Misdescribed amendments**

A misdescribed amendment is an amendment that does not accurately describe the amendment to be made. If, despite the misdescription, the amendment can be given effect as intended, the amendment is incorporated into the compiled law and the abbreviation “(md)” added to the details of the amendment included in the amendment history.

If a misdescribed amendment cannot be given effect as intended, the abbreviation “(md not incorp)” is added to the details of the amendment included in the amendment history.

Endnote 2—Abbreviation key

|  |  |
| --- | --- |
| A = Act | o = order(s) |
| ad = added or inserted | Ord = Ordinance |
| am = amended | orig = original |
| amdt = amendment | par = paragraph(s)/subparagraph(s) |
| c = clause(s) | /sub‑subparagraph(s) |
| C[x] = Compilation No. x | pres = present |
| Ch = Chapter(s) | prev = previous |
| def = definition(s) | (prev…) = previously |
| Dict = Dictionary | Pt = Part(s) |
| disallowed = disallowed by Parliament | r = regulation(s)/rule(s) |
| Div = Division(s) | Reg = Regulation/Regulations |
| exp = expires/expired or ceases/ceased to have | reloc = relocated |
| effect | renum = renumbered |
| F = Federal Register of Legislative Instruments | rep = repealed |
| gaz = gazette | rs = repealed and substituted |
| LI = Legislative Instrument | s = section(s)/subsection(s) |
| LIA = *Legislative Instruments Act 2003* | Sch = Schedule(s) |
| (md) = misdescribed amendment can be given | Sdiv = Subdivision(s) |
| effect | SLI = Select Legislative Instrument |
| (md not incorp) = misdescribed amendment | SR = Statutory Rules |
| cannot be given effect | Sub‑Ch = Sub‑Chapter(s) |
| mod = modified/modification | SubPt = Subpart(s) |
| No. = Number(s) | underlining = whole or part not |
|  | commenced or to be commenced |

Endnote 3—Legislation history

| Name | Registration | Commencement | Application, saving and transitional provisions |
| --- | --- | --- | --- |
| Health Insurance (Section 3C Co‑Dependent Pathology Services) Determination 2018 | 21 June 2018 (F2018L00810) | 1 July 2018 | — |
| Health Insurance (Section 3C Co‑Dependent Pathology Services) Amendment Determination 2018 | 26 October 2018 (F2018L01473) | 1 November 2018 | — |
| Health Insurance (Section 3C Co‑Dependent Pathology Services) Amendment Determination (No.2) 2018 | 30 October 2018 (F2018L01505) | 1 November 2018 | — |
| Health Insurance (Section 3C Co‑Dependent Pathology Services) Amendment Determination (No. 3) 2018 | 17 December 2018 (F2018L01776) | 1 January 2019 (s 2) | — |
| Health Insurance (Section 3C Co‑Dependent Pathology Services) Amendment Determination 2019 | 17 January 2019 (F2019L00044) | 1 February 2019 (s 2) | — |
| Health Insurance (Section 3C Co‑Dependent Pathology Services) Amendment Determination (No.2) 2019 | 22 February 2019 (F2019L00174) | 1 March 2019 (s 2) | — |
| Health Insurance (Section 3C Co‑Dependent Pathology Services) Amendment Determination (No. 3) 2019 | 30 October 2019 (F2019L01385) | 1 November 2019 (s 2(1) item 1) | — |
| Health Insurance (Section 3C Co‑Dependent Pathology Services) Amendment Determination (No. 1) 2020 | 25 March 2020 (F2020L00304) | 1 April 2020 (s 2(1) item 1) | — |
| Health Insurance (Section 3C Co-Dependent Pathology Services) Amendment Determination (No. 4) 2020 | 30 April 2020 (F2020L00521) | 1 May 2020 (s 2(1) item 1) | — |
| Health Insurance (Section 3C Co-Dependent Pathology Services) Amendment Determination (No. 5) 2020 | 23 July 2020 (F2020L00938) | 1 August 2020 (s 2(1) item 1) | — |
| Health Insurance (Section 3C Co-Dependent Pathology Services) Amendment Determination (No. 6) 2020 | 27 August 2020 (F2020L01075) | 1 September 2020 (s 2(1) item 1) | — |
| Health Insurance (Section 3C Co-Dependent Pathology Services) Amendment Determination (No. 7) 2020 | 18 December 2020 (F2020L01642) | 1 January 2021 (s 2(1) item 1) | — |
| Health Insurance (Section 3C Co-Dependent Pathology Services) Amendment Determination 2021 | 16 September 2021 (F2021L01270) | 1 November 2021 (s 2(1) item 1) | — |

Endnote 4—Amendment history

| Provision affected | How affected |
| --- | --- |
| s 2 | rep LA s 48D |
| s 4 | rep LA s 48C |
| s 6 | am F2018L01505 |
| **Schedule 1** |  |
| Schedule 1 | ad F2018L01473 |
|  | rs F2018L01505 |
|  | am F2018L01776; F2019L00044; F2019L00174; F2019L01385; F2020L00304; F2020L00521; F2020L00938; F2020L01075; F2020L01642; F2021L01270 |