EXPLANATORY STATEMENT

Health Insurance Act 1973

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

Subsection 3C(1) of the *Health Insurance Act 1973* (the Act) provides that the Minister may, by legislative instrument, determine that a health service not specified in an item in the pathology services table (the Table) shall, in specified circumstances and for specified statutory provisions, be treated as if it were specified in the Table.

The Table is set out in the regulations made under section 4A of the Act. The most recent version of the regulations is the *Health Insurance (Pathology Services Table) Regulations 2020*.

This instrument relies on subsection 33(3) of the *Acts Interpretation Act 1901* (AIA). Subsection 33(3) of the AIA provides that where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character (including rules, regulations or by-laws), the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument.

Purpose

The purpose of the *Health Insurance (Section 3C Co-Dependent Pathology Services) Amendment Determination 2021* (the Determination) is to amend the *Health Insurance (Section 3C Co-Dependent Pathology Services) Determination 2018* from 1 November 2021. This amendment will align items 72814, 73337, 73341 and 73344 with changes to the Pharmaceutical Benefits Scheme (PBS) which exclude the need for positive programmed cell death ligand 1 (PD-L1) status for access the drug pembrolizumab. The Determination will also amend item 73343 to include genome wide micro-array in addition to fluorescence *in situ* hybridisation (FISH) testing.

Amendment to item 72814

Item 72814 commenced on 1 November 2018 as a new immunohistochemistry test for the evaluation of PD-L1 expression in patients diagnosed with metastatic non-small cell lung cancer (NSCLC) to fulfill requirements for access to pembrolizumab under the PBS.

The Determination will amend item 72814 to remove the requirement of positive PD-L1 status for access to pembrolizumab under the PBS.

Amendment to item 73337

Item 73337 commenced on 1 January 2014 for the testing of tumour tissue from a patient diagnosed with NSCLC, to determine epidermal growth factor receptor (EGFR) gene status as a requirement for access to erlotinib or gefitinib under the PBS.

On 1 July 2018, item 73337 was amended to expand its scope to cover testing for access to afatinib under the PBS. On 1 January 2021, item 73337 was amended to state the therapeutic class "EGFR tyrosine kinase inhibitors" for inclusivity, rather than specifying individual PBS-subsidised medicines. This amendment expanded the item to include the drugs erlotinib, gefitinib and afatinib, as well as osimertinib and any future EGFR tyrosine kinase inhibitors to be listed on the PBS.

The Determination will amend item 73337 to provide that the service may be used to determine whether a patient's requirements relating to EGFR status for access to pembrolizumab under the PBS are fulfilled.

Amendment to item 73341

Item 73341 commenced on 1 July 2015 for FISH testing of tumour tissue from a patient with locally advanced or metastatic NSCLC with documented anaplastic lymphoma kinase (ALK) gene rearrangement status by immunohistochemistry (IHC) and absence of EGFR gene variations, to determine requirements relating to ALK status for access to crizotinib under the PBS. On 1 February 2017 and 17 February 2018, the item was expanded to include testing for access to PBS-listed ceritinib and alectinib respectively, as treatment options.

On 1 May 2020, item 73341 was further amended to state the therapeutic class "ALK inhibitors" for inclusivity, in place of specifying individual PBS-subsidised medicines. This amendment expanded the item to include the drugs crizotinib, ceritinib, alectinib, as well as brigatinib and any future ALK inhibitors to be listed on the PBS. This change also enabled access to PBS-listed treatment options for a specialist or consultant physician consideration of individual patient circumstances, resulting in optimal care for patients.

The Determination will amend item 73341 to provide that, in the absence of targetable EGFR gene variations, the service may be used to determine whether a patient's requirements relating to ALK status for access to pembrolizumab under the PBS are fulfilled.

Amendment to item 73343

Item 73343 commenced on 1 September 2017 for 17p deletion testing by FISH in patients with relapsed or refractory chronic lymphoid leukemia or small lymphocytic lymphoma for access to idelaisib under the PBS. On 1 December 2017, 1 March 2019 and 1 September 2020, the item was expanded to include access to PBS-listed ibrutinib, ventoclax or acalabrutinib respectively, as treatment options.

The Determination will amend item 73343 to allow for the detection of 17p chromosomal deletions by genome wide micro-array (GMWA) as an alternative to FISH. The schedule fee of item 73343 will also increase from $230.95 to $589.90 to reflect clinical practice, and to align the schedule fee with the fee for new item 73391. Item 73391 will be introduced on 1 November 2021 for GMWA testing for people with multiple myeloma in the *Health Insurance Legislation Amendment (2021 Measures No. 2) Regulations 2021*.

Amendment to item 73344

Item 73344 commenced on 1 January 2019 for FISH testing of tumour tissues from a patient with locally advanced or metastatic NSCLC, with documented absence of EGFR and ALK gene variations, for identification of ROS proto-oncogene 1 (ROS1) gene rearrangement status by immunohistochemistry (IHC) for access to entrectinib under the PBS.

On 1 August 2020, item 73344 was amended to enable testing for the ROS1 gene rearrangement to determine eligibility for newly PBS-subsidised entrectinib, in addition to crizotinib.

The Determination will amend item 73344 to provide that, in the absence of targetable EGFR and ALK gene variations, the service may be used to determine whether a patient's requirements relating to ROS1 status for access to pembrolizumab under the PBS are fulfilled.

Consultation
MSAC reviews new or existing medical services or technology, and makes recommendations as to the circumstances under which public funding should be supported. This includes the listing of new items, or amendments to existing items on the MBS.

As part of the MSAC process, consultation was undertaken with key stakeholders, including clinical experts and providers, and consumer health representatives.

Details of the Determination are set out in the Attachment.

The Determination commences on 1 November 2021.

The Determination is a legislative instrument for the purposes of the *Legislation Act 2003*.

Authority: Subsection 3C(1) of the *Health Insurance Act 1973*

ATTACHMENT

Details of the *Health Insurance (Section 3C Co-Dependent Pathology Services) Amendment Determination 2021*

Section 1 – Name

Section 1 provides for the Determination to be referred to as the *Health Insurance (Section 3C Co-Dependent Pathology Services) Amendment Determination 2021*.

Section 2 – Commencement

Section 2 provides that the Determination commences on 1 November 2021.

Section 3 – Authority

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

Section 4 – Schedules

Section 4 provides that each instrument that is specified in a Schedule to this Determination is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this Determination has effect according to its terms.

Schedule 1 – Amendments

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

Item 1 – Schedule 1 (cell at item 72814, column 2)
Item 1 repeals and replaces the descriptor of item 72814 to remove the requirement that the service is to determine if the requirements relating to programmed cell death ligand 1 (PD-L1) status for access to pembrolizumab under the PBS are fulfilled. The updated descriptor specifies that item 72814 is for an immunohistochemical examination using the PD-L1 antibody of tumour material from a patient diagnosed with non-small cell lung cancer.

Item 2 – Schedule 1 (cell at item 73337, column 2)
Item 2 repeals and replaces the descriptor of item 73337 to expand the service to include provision of the test to determine if the requirements relating to EGFR gene status for access to pembrolizumab under the PBS are fulfilled in patients diagnosed with NSCLC.

The updated item descriptor will continue to include services where the test is provided to determine if requirements relating to if EGFR gene status for access to an EGFR tyrosine kinase inhibitors under the PBS are fulfilled.

Item 3 – Schedule 1 (cell at item 73341, column 2)
Item 3 repeals and replaces the descriptor of item 73341 to expand the service to include provision of the test to determine if the requirements relating to ALK gene status for access to pembrolizumab under the PBS are fulfilled in patients diagnosed with NSCLC.

The updated item descriptor will continue to include services where the test is provided to determine if requirements relating to ALK gene rearrangement status for access to ALK inhibitors under PBS are fulfilled.

Item 4 – Schedule 1 (item 73343)
Item 4 repeals and replaces item 73343 to expand the 17p chromosomal deletion testing options for services provided under the item to include GMWA, as an alternative to FISH, in patients with relapsed or refractory chronic lymphoid leukemia or small lymphocytic lymphoma. The change will also clarify the item claiming restrictions of once per 12 months for any particular patient and update the schedule fee of the item from $230.95 to $589.90.

The updated item descriptor will continue to include services where the test is provided to determine if requirements relating to 17p chromosomal deletion status for access to idelaisib, ibrutinib, venetoclax or acalabrutinib under the PBS are fulfilled.

Item 5 – Schedule 1 (cell at item 73344, column 2)
Item 5 repeals and replaces the descriptor of item 73344 to expand the service to include provision of the test to determine if the requirements relating to ROS1 gene status for access to pembrolizumab under PBS are fulfilled in patients diagnosed with NSCLC.

The updated item descriptor will continue to include services where the test is provided to determine if requirements relating to ROS1 gene arrangement status for access to crizotinib or entrectinib under the PBS are fulfilled.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

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

This instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in Section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Determination

The purpose of the *Health Insurance (Section 3C Co-Dependent Pathology Services) Amendment Determination 2021* (the Determination) is to amend the *Health Insurance (Section 3C Co-Dependent Pathology Services) Determination 2018* from 1 November 2021. This amendment will align items 72814, 73337, 73341 and 73344 with changes to the Pharmaceutical Benefits Scheme (PBS) which exclude the need for positive programmed cell death ligand 1 (PD-L1) status for access the drug pembrolizumab.

The Determination will also amend item 73343 to include genome wide micro-array in addition to fluorescence *in situ* hybridisation (FISH) testing, and to increase the schedule fee from $230.95 to $589.90 to reflect clinical practice, and to align the schedule fee with the fee for new item 73391. Item 73391 will be introduced on 1 November 2021 for GMWA testing for people with multiple myeloma in the *Health Insurance Legislation Amendment (2021 Measures No. 2) Regulations 2021*.

Human rights implications

This instrument engages Articles 9 and 12 of the International Covenant on Economic Social and Cultural Rights (ICESCR), specifically the rights to health and social security.

The Right to Health

The right to the enjoyment of the highest attainable standard of physical and mental health is contained in Article 12(1) of the ICESCR. The UN Committee on Economic Social and Cultural Rights (the Committee) has stated that the right to health is not a right for each individual to be healthy, but is a right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.

The Committee reports that the *'highest attainable standard of health'* takes into account the country's available resources. This right may be understood as a right of access to a variety of public health and health care facilities, goods, services, programs, and conditions necessary for the realisation of the highest attainable standard of health.

The Right to Social Security

The right to social security is contained in Article 9 of the ICESCR. It requires that a country must, within its maximum available resources, ensure access to a social security scheme that provides a minimum essential level of benefits to all individuals and families that will enable them to acquire at least essential health care. Countries are obliged to demonstrate that every effort has been made to use all resources that are at their disposal to satisfy, as a matter of priority, this minimum obligation.

The Committee reports that there is a strong presumption that retrogressive measures taken in relation to the right to social security are prohibited under ICESCR. In this context, a

retrogressive measure would be one taken without adequate justification that had the effect of reducing existing levels of social security benefits, or of denying benefits to persons or groups previously entitled to them. However, it is legitimate for a Government to re-direct its limited resources in ways that it considers to be more effective at meeting the general health needs of all society, particularly the needs of the more disadvantaged members of society.

Analysis

This instrument advances the right to health and the right to social security by aligning items 72814, 73337, 73341, and 73344 with changes to the Pharmaceutical Benefits Scheme (PBS) to exclude the need for positive programmed cell death ligand 1 (PD-L1) status for access the drug pembrolizumab. These changes will ensure that, through these subsidised pathology services, more patients with NSCLC will be eligible to receive targeted treatments and will also be considered eligible for treatment with pembrolizumab in the absence of targetable tumour variants.

The instrument also expands item 73343 to enable genome wide micro-array in addition to fluorescence in-situ hybridisation (FISH) testing, which will provide an alternative testing method. The instrument also increases the schedule fee for item 73343 to reflect clinical practice, and to align the schedule fee with the fee for new item 73391, which will be introduced on 1 November 2021 for GMWA testing for people with multiple myeloma

Conclusion

This instrument is compatible with human rights as it advances the right to health and the right to social security.

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