**EXPLANATORY STATEMENT**

*Health Insurance Act 1973*

*Health Insurance (Section 3C Co-Dependent Pathology Services) Amendment Determination (No. 5) 2022*

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 AIAprovides 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 (No. 5) 2022* (the Amendment Determination) is to amend the *Health Insurance (Section 3C Co-Dependent Pathology Services) Determination 2018* (Co-Dependent Pathology Services Determination). Under this Amendment Determination, item 72814, which provides a Medicare benefit for programmed Cell Death Ligand 1 (PD-L1) immunohistochemistry testing of tumour material from a patient diagnosed with non‑small cell lung cancer, will be amended to also include testing of tumour material from a patient diagnosed with recurrent (not amenable to local treatment) or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx.

At its November 2021 meeting, the Medical Services Advisory Committee (MSAC) supported the amendment of item 72814 to also include PD-L1 testing for patients with recurrent or metastatic head and neck squamous cell carcinoma. Following the support of MSAC, the Pharmaceutical Benefits Advisory Committee (PBAC) supported the listing of pembrolizumab on the Pharmaceutical Benefits Scheme (PBS) for the first-line treatment of recurrent or metastatic squamous cell carcinoma of the head and neck at its March 2022 meeting.

This Amendment Determination will enable Medicare benefits to be paid for PD-L1 immunohistochemistry testing of tumour material from a patient diagnosed with recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx to determine a patient’s suitability for PBS listed pembrolizumab as a first-line treatment for recurrent or metastatic head and neck squamous cell carcinoma.

**Consultation**

MSAC reviews new or existing medical services or technology, and the circumstances under which public funding should be supported through listing on the Medicare Benefits Schedule (MBS). This includes the listing of new items, or amendments to existing items on the MBS.

The Royal College of Pathologists of Australasia was consulted in regard to this amendment and were generally supportive. One consumer organisation, Head and Neck Cancer Australia, provided feedback during the MSAC processes and was supportive of PD-L1 testing and pembrolizumab treatment.

Details of the Amendment Determination are set out in the Attachment.

The Amendment Determination commences on 1 October 2022.

The Amendment 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 (No. 5) 2022***

Section 1 – Name

Section 1 provides for the Amendment Determination to be referred to as the *Health Insurance (Section 3C Co-Dependent Pathology Services) Amendment Determination (No. 5) 2022*.

Section 2 – Commencement

Section 2 provides that the Amendment Determination commences on 1 October 2022.

Section 3 – Authority

Section 3 provides that the Amendment 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 Amendment 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 Amendment Determination has effect according to its terms.

Schedule 1 – Amendments

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

**Amendment item 1** amends item 72814 to allow patients diagnosed with recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx, in addition to patients diagnosed with non‑small cell lung cancer, to access PD-L1 immunohistochemistry testing of tumour material under item 72814. From 1 October 2022, these patients will be able to access a Medicare benefit for item 72814 to determine their PD-L1 status for assessing suitability for PBS listed pembrolizumab as a first-line treatment for recurrent or metastatic squamous cell carcinoma of the head and neck.

**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 (No. 5) 2022*

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 (No. 5) 2022* (the Amendment Determination) is to amend the *Health Insurance (Section 3C Co-Dependent Pathology Services) Determination 2018* (Co-Dependent Pathology Services Determination). Under this Amendment Determination, item 72814, which provides a Medicare benefit for programmed Cell Death Ligand 1 (PD-L1) immunohistochemistry testing of tumour material from a patient diagnosed with non‑small cell lung cancer, will be amended to also include testing of tumour material from a patient diagnosed with recurrent (not amenable to local treatment) or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx.

At its November 2021 meeting, the Medical Services Advisory Committee (MSAC) supported the amendment of item 72814 to also include PD-L1 testing for patients with recurrent or metastatic head and neck squamous cell carcinoma. Following the support of MSAC, the Pharmaceutical Benefits Advisory Committee (PBAC) supported the listing of pembrolizumab on the PBS for the first-line treatment of recurrent or metastatic squamous cell carcinoma of the head and neck at its March 2022 meeting.

This Amendment Determination will enable Medicare benefits to be paid for PD-L1 immunohistochemistry testing of tumour material from a patient diagnosed with recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx to determine a patient’s suitability for PBS listed pembrolizumab as a first-line treatment for recurrent or metastatic head and neck squamous cell carcinoma.

**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 in an effort 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.

*The right of equality and non-discrimination*

The rights of equality and non-discrimination are contained in articles 2, 16 and 26 of the International Covenant on Civil and Political Rights (ICCPR).  Article 26 of the ICCPR requires that all persons are equal before the law, are entitled without any discrimination to the equal protection of the law and in this respect, the law shall prohibit any discrimination and guarantee to all persons equal and effective protection against discrimination on any ground such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.

Analysis

This instrument advances the existing rights to health, the right to social security and the right of equality and non-discrimination by providing patients with access to Medicare benefits for PD-L1 immunohistochemistry testing of tumour material from a patient diagnosed with recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx to determine the patient’s suitability for PBS listed pembrolizumab as a first-line treatment for recurrent or metastatic head and neck squamous cell carcinoma.

**Conclusion**

This instrument is compatible with human rights as it advances the right to health, the right to social security and the right of equality and non-discrimination.

**Nigel Murray**

**Assistant Secretary**

**MBS Policy and Specialist Services**

**Medical Benefits Division**

**Department of Health and Aged Care**