EXPLANATORY STATEMENT

Issued by the Minister for Health and Ageing

*Health Insurance Act 1973*

*Health Insurance Legislation Amendment (2025 Measures No. 2) Determination 2025*

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 subsection 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 Legislation Amendment (2025 Measures No. 2) Determination 2025* (the Amendment Determination) is to amend the *Health Insurance (Section 3C Co-Dependent Pathology Services) Determination 2018* (Co-Dependent Pathology Determination)and the *Health Insurance (Pathologist-determinable Services) Determination 2015* (Pathologist-determinable Determination) to introduce a new Medicare Benefits Schedule (MBS) item to determine a patient’s eligibility for a relevant treatment under the Pharmaceutical Benefits Scheme (PBS) from 1 July 2025, as a pathologist-determinable service.

Schedules 1 and 2 of the Amendment Determination respectively introduce the new MBS item 73319 and establish the item as a pathologist-determinable service.

The new item 73319 is for *IDH1* variant testing in tumour tissue for the purpose of determining eligibility for a relevant treatment under the PBS in patients with histologically confirmed cholangiocarcinoma. Testing is limited to once per lifetime for patients. The new item commences on 1 July 2025, to coincide with the listing of ivosidenib on the PBS, which is a relevant treatment for the clinical indication described in the new item 73319. The test will be used to identify which patients with cholangiocarcinoma are suitable for treatment with ivosidenib and for future, relevant treatments which may be listed on the PBS for the same clinical indication.

At its meeting on 29 November 2024, the Medical Services Advisory Committee (MSAC) supported MSAC application 1750 for the creation of the new MBS item for tumour tissue *IDH1* variant testing of patients with histologically confirmed cholangiocarcinoma. MSAC noted that the Pharmaceutical Benefits Advisory Committee had recommended ivosidenib for treatment of locally advanced or metastatic cholangiocarcinoma with an *IDH1* variant, in patients who have previously progressed on chemotherapy. MSAC considered the testing was safe, the cost to the MBS was acceptable, and if it provided access to ivosidenib on the PBS, then this test would improve health outcomes for the subset of patients with cholangiocarcinoma who harbour an *IDH1* variant. MSAC acknowledged the high clinical unmet need in the defined population that would be met by access to this test, noting that improved health outcomes were shown for cholangiocarcinoma patients with *IDH1* variants treated with ivosidenib.

**Consultation**

The Department of Health, Disability and Ageing consulted with the following organisations regarding the proposed new MBS item for tumour tissue *IDH1* variant testing as part of the MSAC targeted consultation process:

* Australasian Gastro-Intestinal Trials Group
* Australian Genomic Cancer Medicine Centre Limited (Omico)
* Australian Pathology
* Cholangiocarcinoma Foundation Australia
* Clinical Oncological Society of Australia
* Gastroenterological Society of Australia
* GI Cancer Institute
* Medical Oncology Group of Australia (specialty society of RACP)
* Private Cancer Physicians of Australia
* Public Pathology Australia
* Rare Cancers Australia
* Royal College of Pathologists of Australasia

The parties that responded were supportive of the proposed new MBS item.

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

The Amendment Determination commences on 1 July 2025.

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

Authority: Subsection 3C(1) of the

 *Health Insurance Act 1973*

ATTACHMENT

Details of the *Health Insurance Legislation Amendment (2025 Measures No. 2) Determination 2025*

Section 1 – Name

Section 1 provides for this instrument to be referred to as the *Health Insurance Legislation Amendment (2025 Measures No. 2) Determination 2025* (Amendment Determination).

Section 2 – Commencement

Section 2 provides for the Amendment Determination to commence on 1 July 2025.

Section 3 – Authority

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

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 – Co-Dependent Pathology Services Amendments

**Item 1** inserts new MBS item 73319 for *IDH1* testing in tumour tissue for the purpose of determining eligibility for a relevant treatment under the PBS in patients with histologically confirmed cholangiocarcinoma into the *Health Insurance (Section 3C Co-Dependent Pathology Services) Determination 2018*.

Schedule 2 –Pathologist-determinable Services Amendments

**Item 1** inserts MBS item 73319 into column 1, item 1 in the table at Section 5 subparagraph (b)(iii) of the *Health Insurance (Pathologist-determinable Services) Determination 2015* which sets out that the pathology service mentioned in item 73319 is a pathologist-determinable service, in relation to which, the pathology service originally requested was an item in the pathology services table that is mentioned in column 2 of the table.

**Item 2** inserts MBS item 73319 into the note under the table at Section 5 subparagraph (b)(iii) which sets out that the item 73319 is specified in a determination made under subsection 3C(1) of the Act.

**Statement of Compatibility with Human Rights**

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

***Health Insurance Legislation Amendment (2025 Measures No. 2) Determination 2025***

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 Amendment Determination**

The purpose of the *Health Insurance Legislation Amendment (2025 Measures No. 2) Determination 2025* (the Amendment Determination) is to amend the *Health Insurance (Section 3C Co-Dependent Pathology Services) Determination 2018* (Co-Dependent Pathology Determination)and the *Health Insurance (Pathologist-determinable Services) Determination 2015* (Pathologist-determinable Determination) to introduce a new Medicare Benefits Schedule (MBS) item 73319 to determine a patient’s eligibility for a relevant treatment under the Pharmaceutical Benefits Scheme (PBS) from 1 July 2025, as a pathologist-determinable service.

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**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 maintains to the rights to health and social security and the right of equality and non-discrimination. The instrument introduces a new MBS service to determine a patient’s eligibility for treatment with ivosidenib under the PBS.

**Conclusion**

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

**Mary Warner**

**Assistant Secretary**

**Diagnostic Imaging and Pathology Branch**

**Medicare Benefits and Digital Health Division**

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**Department of Health, Disability and Ageing**