# EXPLANATORY STATEMENT

Issued by the Authority of the Minister for Health

*Health Insurance Act 1973*

*Health Insurance (Pathologist-determinable Services) Determination 2015*

Section 4BA of the *Health Insurance Act 1973* (the Act) provides for the Minister to determine that a particular pathology service, or pathology services included in a class of pathology services, are pathologist-determinable services, after consultation with Royal College of Pathologists of Australasia.

Section 16A of the Act specifies that certain requirements have to be met for the payment of Medicare benefits in relation to pathology services, including the requirement for a pathology service to be requested (16A(3)). Pathologist- determinable services allow Medicare benefits to be paid for pathology services which are requested and performed by a pathologist for their own patients; or for certain tests which are not requested, but are performed on the basis of information learned from an originally requested service.

The *Health Insurance (Pathologist-determinable Services) Determination 2015* (the Determination) revokes and remakes the *Health Insurance (Pathologist-determinable Services) Determination 2006 (No. 3)* (the previous Determination).

**Purpose**

The purpose of revoking and remaking the previous Determination is to include a reference to a new pathologist-determinable service (item 73342). The new item is for an in-situ hybridisation test of tumour tissue from a patient to determine eligibility to access trastuzumab (for treatment of metastatic gastric cancer) under the Pharmaceutical Benefits Scheme.

The Determination is to allow for the payment of Medicare benefits to cover specific circumstances where:

* pathology services are requested and performed by an Approved Pathology Practitioner (APP) for their own patients.

For example, a haematologist or immunologist performing pathology services for their own patients.

* an original requested service has been rendered by an APP; and
* in light of information from the original requested service, that APP performs another pathology test (a pathologist-determinable service); and
* the original service, and the pathology-determinable test, are in the Determination.

For example, the receipt of a request by a histopathologist for the examination of a biopsy specimen from an operation and following the examination the histopathologist determines that further tests are necessary to complete the diagnosis. The histopathologist would be able to undertake further testing without the need to seek another request from the treating practitioner.

Details of the Determinationare set out in the Attachment.

This Determination is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

This Determination commences on 1 January 2016.

**Consultation**

Consultation was undertaken on the change the Determination. The creation of the new item was considered and agreed to by the Medical Services Advisory Committee (MSAC).

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

As part of the MSAC process, consultation was undertaken with professional bodies, consumer groups, the public and clinical experts for proposals put forward for consideration by the Committee.

Consultation was undertaken with the Royal College of Pathologists of Australasia (RCPA) as part of the MSAC process.

ATTACHMENT

Details of the *Health Insurance (Pathologist-determinable Services) Determination 2015*

Section 1 – Name of Determination

This section provides for the Determination to be referred to as the *Health Insurance (Pathologist-determinable Services) Determination 2015.*

Section 2 – Commencement

This section provides for the Determination to commenceon 1 January 2016.

Section 3 – Revocation

This section revokes the *Health Insurance (Pathologist-determinable Services) Determination 2006 (No. 3).*

Section 4 – Interpretation

Section 4 defines terms used in the Determination.

Section 5 – Pathologist-determinable services

Section 5 provides that the following items in the pathology services table are, when rendered in the circumstances described in the Determination, classes of pathology services that are pathologist-determinable services:

Subsection 5(a):

* a pathology service in the pathology services table that is rendered, by or on behalf of, an approved pathology practitioner to a patient of that practitioner.

Subsection 5(b):

* a pathology service that is rendered by, or on behalf of an approved pathology practitioner where that practitioner considers it to be necessary, on the basis of information learned from another service:
  + that was rendered to the patient by, or on behalf of, that practitioner; and
  + the request is made in writing, or if the request was provided in a form other than writing, confirmed in writing within 14 days and the request is made in accordance with the regulations.
* the original service, and the pathology-determinable test, are specified in the table in the subsection.

Subsection 5(c):

* a pathology service that is mentioned in items 69494, 69495 or 69496 if the service is rendered by, or on behalf of an approved pathology practitioner who is a recognised pathologist, where that practitioner considers it to be necessary on the basis of information provided by the requesting practitioner, the nature or appearance of the specimen, or as a consequence of information resulting from a pathology service mentioned in items 69303, 69306, 69312, 69318, 69321 or 69345.

**Statement of Compatibility with Human Rights**

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

*Health Insurance (Pathologist-determinable Services) Determination 2015*

This Legislative 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 Legislative Instrument**

The Determination revokes and remakes the previous Determination is to include a reference to a new pathologist-determinable service (item 73342). The new item is for an in-situ hybridisation test of tumour tissue from a patient to determine eligibility to access trastuzumab (for treatment of gastric cancer) under the Pharmaceutical Benefits Scheme.

**Human rights implications**

The regulations engage 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.

Analysis

This Determination will advance rights to health and social security by ensuring access to publicly subsidised health services which are clinically effective and cost-effective.

**Conclusion**

This Determination is compatible with the human rights recognised in the *Human Rights (Parliamentary Scrutiny) Act 2011*.

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**Department of Health**