EXPLANATORY STATEMENT

Issued by the Authority of the Minister for Health

*Health Insurance Act 1973*

*Health Insurance (Section 3C Diagnostic Imaging Services – 3D Breast Tomosynthesis) Determination 2018*

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 diagnostic imaging services table shall, in specified circumstances and for specified statutory provisions, be treated as if it were specified in the diagnostic imaging services table.

The diagnostic imaging services table is set out in the regulations made under subsection 4AA(1) of the Act, and is repealed and replaced each year. The table made under this subsection is referred to as the Diagnostic Imaging Services Table (DIST).

**Purpose**

In the 2018-19 Budget under the *Guaranteeing Medicare — Medicare Benefits Schedule Review — response to Taskforce recommendations* measure, the Government agreed to introduce two new interim items for three dimensional breast tomosynthesis (3DBT) services.

3DBT is a relatively new digital mammography technology that produces a 3D image of the breast by using several x-rays obtained at different angles.

Providers have been using a combination of existing items, including items for plain film tomography (items 60100 and 60101), in order to enable patients to claim a benefit for providing a 3DBT service.

Despite being an established practice, it is an evolution in technology that is still to be assessed by the Medical Services Advisory Committee (MSAC). The Diagnostic Imaging Clinical Committee, a subcommittee of the Medicare Benefits Schedule Review Taskforce (the Taskforce), found that plain tomography items would have been obsolete if not for their use on 3DBT. The Taskforce recommended the listing of two new interim items for 3DBT to enable providers to appropriately provide the service while MSAC considers long term funding.

The *Health Insurance (Section 3C Diagnostic Imaging Services – 3D Breast Tomosynthesis) Determination 2018* (the Determination) introduces two items (53902 and 53905) for 3DBT services from 1 November 2018. The services can be performed on patients who have:

* symptoms or indications of breast malignancy; and
* are at a higher risk due to past occurrence of breast malignancy in the patient or the patient’s family.

**Consultation**

The 3DBT interim items in the Determination were released for public consultation prior to finalisation of the recommendations to Government. This was undertaken through public consultation by the Taskforce.

Details of the Determination are set out in the Attachment.

The Determination commences on 1 November 2018.

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 Diagnostic Imaging Services – 3D Breast Tomosynthesis) Determination 2018*

Section 1 – Name

# Section 1 provides for the Determination to be referred to as the *Health Insurance (Section 3C Diagnostic Imaging Services – 3D Breast Tomosynthesis) Determination 2018.*

Section 2 – Commencement

Section 2 provides that the Determination commences on 1 November 2018.

Section 3 – Authority

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

Section 4 – Definitions

Section 4 defines terms used in the Determination.

Section 5 – Treatment of relevant services

Section 5 provides that a clinically relevant service provided in accordance with the Determination shall be treated, for relevant provisions of the *Health Insurance Act 1973* and *National Health Act 1953*, and regulations made under those Acts, as if it were both a professional service and a medical service and as if there were an item specified in the diagnostic imaging services table for the service.

Section 6 – Application of a provision of the diagnostic imaging services table

Section 6 provides that clause 2.3.3 of the diagnostic imaging services table applies to the items in the Schedule so that the items only apply to a mammography service performed:

* under the supervision of a specialist in the specialty of diagnostic radiology who is available to monitor and influence the conduct and diagnostic quality of the examination and if necessary, to attend on the patient personally; or
* if the service is not able to be supervised by a diagnostic radiology specialist and the service is provided in an emergency situation, or the service is provided in a remote location due to medical necessity.

Schedule – Relevant services

The Schedule lists items 59302 and 59305 for 3DBT services.

**Statement of Compatibility with Human Rights**

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

***Health Insurance (Section 3C Diagnostic Imaging Services – 3D Breast Tomosynthesis) Determination 2018***

This Determination 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 Diagnostic Imaging Services – 3D Breast Tomosynthesis) Determination 2018* (the Determination) is to enable two interim items for three dimensional breast tomosynthesis (3DBT) mammography services. The services can be performed on patients who have:

* symptoms or indications of breast malignancy; and
* are at a higher risk due to past occurrence of breast malignancy in the patient or the patient’s family.

3DBT is a relatively new digital mammography technology that produces a 3D image of the breast by using several x-rays obtained at different angles.

Providers have been using a combination of existing items, including items for plain film tomography (items 60100 and 60101), in order to enable patients to claim a benefit for providing a 3DBT service.

Despite being an established practice, it is an evolution in technology that is still to be assessed by the Medical Services Advisory Committee (MSAC). The Diagnostic Imaging Clinical Committee, a subcommittee of the Medicare Benefits Schedule Review Taskforce (the Taskforce), found that plain tomography items would have been obsolete if not for their use on 3DBT.

The Taskforce recommended the listing of two new interim items for 3DBT to enable providers to appropriately provide the service while the MSAC considers long term funding.

**Human rights implications**

This Determination 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.

Analysis

This Determination advances the right to health and the right to social security by ensuring access to publicly subsidised health services which are clinically effective, safe and cost-effective.

**Conclusion**

This Determination is compatible with human rights as it has a positive effect on the right to health and the right to social security.

**Celia Street**

**Assistant Secretary**

**Diagnostic Imaging and Pathology Branch**

**Medical Benefits Division**

**Department of Health**