

## EXPLANATORY STATEMENT

Issued by the Authority of the Minister for Health

*Health Insurance Act 1973*

*Health Insurance (Section 3C Diagnostic Imaging – Nuclear Medicine Services) Amendment Determination 2019*

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The diagnostic imaging services table is set out in the regulations made under subsection 4AA(1) of the Act, which is repealed and remade each year. The most recent version of the regulations is the *Health Insurance (Diagnostic Imaging Services Table) Regulations 2019*.

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**

On 14 September 2019, six items were listed on the Medicare Benefits Schedule (MBS) to allow patients to continue accessing certain nuclear medicine services during a shortage in supply of radiopharmaceuticals. The items are prescribed in the *Health Insurance (Section 3C Diagnostic Imaging – Nuclear Medicine Services) Determination 2019* (the Principal Determination).

The purpose of the *Health Insurance (Section 3C Diagnostic Imaging – Nuclear Medicine Services) Amendment Determination 2019* (the Determination) is to amend the Principal Determination to clarify the item requirements of nuclear medicine services, and to introduce a new item (61344) for anatomic localisation or attenuation correction for use in association with the items.

The purpose of this Determination is to ensure that patients can receive Medicare benefits for nuclear medicine services. These services are essential for the diagnosis and management of various health conditions. To this effect, the amendments in the Schedule are taken to have commenced immediately after the Principal Determination commenced. This is to ensure that patients will continue to be able to receive Medicare benefits for nuclear medicine services and will not be disadvantaged during a shortage in supply of radiopharmaceuticals. Although Schedule 1 applies retrospectively, it is not contrary to section 12 of the *Legislation Act 2003* as it does not disadvantage a person and only imposes a liability on the Commonwealth for the retrospective period.

### **Consultation**

The Australasian Association of Nuclear Medicine Specialists and the Australian Diagnostic Imaging Association were consulted in the development of the Determination.

Details of the Determination are set out in the [Attachment](#).

The Determination commences immediately after registration.

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

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

**Details of the *Health Insurance (Section 3C Diagnostic Imaging – Nuclear Medicine Services) Amendment Determination 2019***

Section 1 – Name

Section 1 provides for the instrument to be referred to as the *Health Insurance (Section 3C Diagnostic Imaging – Nuclear Medicine Services) Amendment Determination 2019*.

Section 2 – Commencement

Section 2 provides that the instrument commences immediately after registration. The amendments in Schedule 1 are taken to have commenced immediately after commencement of the *Health Insurance (Section 3C Diagnostic Imaging – Nuclear Medicine Services) Determination 2019* commenced (14 September 2019).

Section 3 – Authority

Section 3 provides that the instrument 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 instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1 – Amendments

*Health Insurance (Section 3C Diagnostic Imaging – Nuclear Medicine Services) Determination 2019* (Principal Determination)

**Item 1 – Section 6 – Application of Items in Schedule 1**

Section 6 of the Principal Determination applies paragraph (a) of clause 2.4.1 of the diagnostic imaging services table to item 61333, and paragraphs (b) and (c) of clause 2.4.1 of the diagnostic imaging services table to items 61311, 61332, 61336, 61337 and 61341.

The Determination amends Section 6 so that paragraph 2.4.1(a) no longer applies to any items in the Determination.

Paragraphs 2.4.1(b) and (c) now applies to all items in Schedule 1, including the new item 61344.

**Item 2 – Schedule 1 (table)**

Schedule 1 of the Principal Determination provides a table that prescribes the fee and item descriptors for a service to which items 61311, 61332, 61333, 61336, 61337 and 61341 applies.

Item 2 repeals this table and prescribes a new table that provides amended item descriptors for items 61311, 61332, 61333, 61336, 61337 and 61341. The table also prescribes new item 61344 for anatomic localisation or attenuation correction for use in association with the items 61311, 61332, 61333, 61336, 61337 and 61341.

The amended item descriptors remove the reference to planar imaging and computed tomography to clarify the intent of the items. The lung perfusion and ventilation study, item 61333, has been amended to remove the reference to single photon emission tomography and planar imaging, as this scan must be performed using PET. A further change to item 61333, removes the references to two currently approved radiopharmaceuticals which are not in short supply, and will ensure the temporary item is used in association with the newly approved radiopharmaceuticals under the Therapeutic Goods Administration (TGA) Special Access Scheme (SAS).

Undertaking anatomic localisation is integral to correctly interpreting the diagnostic information provided in association with the temporary PET items. Currently, item 61505 in the diagnostic imaging services table is for anatomic localisation or attenuation correction and can be used in association with items 61302 to 61729. However, the items listed in the Principal Determination cannot be used with item 61505. To address this issue, a new item 61344 is listed to enable anatomic localisation attenuation correction services to be used in association with the temporary items.

## 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 – Nuclear Medicine Services) Amendment Determination 2019***

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**

On 14 September 2019, six items were listed on Medicare Benefits Schedule (MBS) to allow patients continued access to certain nuclear medicine services during a shortage in supply of radiopharmaceuticals. The items are prescribed in the *Health Insurance (Section 3C Diagnostic Imaging – Nuclear Medicine Services) Determination 2019* (the Principal Determination).

The purpose of the *Health Insurance (Section 3C Diagnostic Imaging – Nuclear Medicine Services) Amendment Determination 2019* (the Determination) is to amend the Principal Determination to clarify the item descriptors for the temporary nuclear medicine items, and to introduce a new item for anatomic localisation or attenuation correction for use in association with the items.

#### **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.

Analysis

This instrument will maintain rights to health and social security by ensuring patients can continue to access subsidised nuclear medicine services on the Medicare Benefits Schedule.

**Conclusion**

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

**Liz Dowd**  
**A/g First Assistant Secretary**  
**Medical Benefits Division**  
**Health Financing Group**  
**Department of Health**