

EXPLANATORY STATEMENT

Health Insurance Act 1973

Health Insurance (Section 3C Diagnostic Imaging Services – Nuclear Medicine Services) Amendment (PET and Technetium-99m) Determination 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 Diagnostic Imaging 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 4AA of the Act. The most recent version of the regulations is the *Health Insurance (Diagnostic Imaging Services Table) Regulations (No. 2) 2020*.

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

The purpose of the *Health Insurance (Section 3C Diagnostic Imaging Services – Nuclear Medicine Services) Amendment (PET and Technetium-99m) Determination 2022* (the Amendment Determination) is to amend the *Health Insurance (Section 3C Diagnostic Imaging – Nuclear Medicine Services) Determination 2019* (the Principal Determination) by making changes to items 61333, 61336 and 61341 and repealing nine items.

The changes to items 61333, 61336 and 61341 will provide patient access to alternative positron emission tomography (PET) imaging services, during supply disruptions of the radiopharmaceutical technetium-99m (Tc-99m), to enable continuity of patient care rather than delayed care, by ensuring patients continue to have affordable access to an appropriate diagnostic imaging service. The Amendment Determination will enable providers to substitute a PET imaging scan when a preferred Tc-99m based scan under items 61348, 61402, 61421, or 61425 has been requested and is not available due to the supply interruption. These changes will enable medical practitioners to be more responsive and better able to reschedule patients to use PET items as required. The amended PET items will be available on an ongoing basis to allow medical practitioners to provide these services in shorter periods of supply disruption, with the items available for use as soon as a shortage is identified.

The Amendment Determination will also repeal items 61311, 61332, 61365, 61377, 61380, 61418, 61422 (myocardial perfusion studies using PET items), 61337 (bone study with PET items) and 61344 (CT attenuation correction or anatomic localisation items). Stakeholder feedback and utilisation data indicated that the myocardial perfusion studies using PET items were of limited use during previous Tc-99m supply disruptions, the bone study with PET

item duplicates other service items, and the CT attenuation correction or anatomic localisation item is obsolete and can be claimed through existing item 61505.

The Government supported and announced this change in the 2022-23 Budget under the *Guaranteeing Medicare – Medical Benefits Schedule new and amended listings* measure, as well as being endorsed by the Medical Services Advisory Committee (MSAC) Executive, at their 29 October 2021 meeting.

This Amendment Determination will commence on 1 November 2022.

Consultation

The Department of Health and Aged Care has consulted with key stakeholders including members of the Australasian Association of Nuclear Medicine Specialists (AANMS), the Royal Australian and New Zealand College of Radiologists (RANZCR), the Australian Diagnostic Imaging Association (ADIA), the Australian and New Zealand Society of Nuclear Medicine (ANZSNM) and the Rural Alliance in Nuclear Scintigraphy (RAINS).

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

The Amendment Determination commences on the 1 November 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 Diagnostic Imaging Services – Nuclear Medicine Services) Amendment (PET and Technetium-99m) Determination 2022*Section 1 – Name

Section 1 provides for the Amendment Determination to be referred to as the *Health Insurance (Section 3C Diagnostic Imaging Services – Nuclear Medicine Services) Amendment (PET and Technetium-99m) Determination 2022*.

Section 2 – Commencement

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

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

Amendment item 1 amends section 4(1) of the *Health Insurance (Section 3C Diagnostic Imaging – Nuclear Medicine Services) Determination 2019* (the Principal Determination) to remove the definitions of Modified Monash areas 3 to 7 as the items with references to these terms are being repealed (refer to **amendment item 5**).

Amendment item 2 defines terms used in the Amendment Determination.

Amendment item 3 repeals and replaces section 6 of the Principal Determination. The amended section 6 provides the provisions of the diagnostic imaging services table that apply as if items 61333, 61336 and 61341 were specified in the relevant provision in the diagnostic imaging services table. The repealed section 6 no longer applies as the items to which this provision relates are being repealed (refer to **amendment item 5**).

Subsection 6(1) will provide that items 61333, 61336 and 61341 will be treated as if they were specified in clause 1.2.17 of the diagnostic imaging services table. In accordance with clause 1.2.17, the practitioner who provides the service under item 61333, 61336 or 61341

must give a report of the service performed to the practitioner who requested the service under item 61348, 61402, 61421 or 61425.

Subsection 6(2) will provide that clause 2.4.2 of the diagnostic imaging services table does not apply to items 61333, 61336 and 61341. Clause 2.4.2 provides the general requirements for PET nuclear scanning services. New sections 8 to 11 (refer to **amendment item 4**) will provide the requirements for PET nuclear scanning services under amended items 61333, 61336 and 61341 (refer to **amendment item 5**).

Amendment item 4 repeals and replaces section 7 of the Principal Determination and introduces sections 8 to 11. Paragraph 7(1)(a) will provide that an item in Schedule 1 of the instrument only applies to a service described in the item if the patient's clinical condition requires the service to be performed before the resumption of normal technetium-99m supply is anticipated by the practitioner who provides the service on a case-by-case basis.

Paragraph 7(1)(b) will provide that an item in Schedule 1 of the instrument only applies to a service described in the item if the report of the service performed includes a justification for the substitute service, which describes the unavailability of a service to which item 61348, 61402, 61421 or 61425 applies.

The repealed section 7 provides that items in Schedule 1 of the instrument only apply during the periods specified in Schedule 2. This provision is no longer relevant as Schedule 2 is being repealed to allow for items in Schedule 1 to be provided on an ongoing basis when disruptions to the supply of technetium-99m occur (refer to **amendment item 6**).

New sections 8 to 11 will provide the requirements for PET services under amended items 61333, 61336 and 61341. Section 8 provides that the service must be performed in a comprehensive facility.

Amendment item 5 amends Schedule 1 of the Principal Determination to amend three items (61333, 61336 and 61341) and repeal nine items (61311, 61332, 61365, 61377, 61380, 61418, 61422, 61337 and 61344) for nuclear medicine imaging services.

Amended item 61333 will only apply to a service described in the item if the service is performed because the service to which item 61348 applies cannot be performed due to unavailability of technetium-99m.

Amended item 61336 will only apply to a service described in the item if the service is performed because the service to which item 61402 applies cannot be performed due to unavailability of technetium-99m.

Amended item 61341 will only apply to a service described in the item if the service is performed because the services to which item 61421 or 61425 apply cannot be performed due to unavailability of technetium-99m.

Amendment item 6 repeals Schedule 2 of the Principal Determination to allow for items listed in Schedule 1 to be accessed on an ongoing basis when disruptions to the supply of technetium-99m occur.

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 – Nuclear Medicine Services) Amendment (PET and Technetium-99m) Determination 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 Diagnostic Imaging Services – Nuclear Medicine Services) Amendment (PET and Technetium-99m) Determination 2022* (the Amendment Determination) is to amend the *Health Insurance (Section 3C Diagnostic Imaging – Nuclear Medicine Services) Determination 2019* (the Principal Determination) by making changes to items 61333, 61336 and 61341 and repealing nine items.

The changes to items 61333, 61336 and 61341 will provide patient access to alternative positron emission tomography (PET) imaging services, during supply disruptions of the radiopharmaceutical technetium-99m (Tc-99m), to enable continuity of patient care rather than delayed care, by ensuring patients continue to have affordable access to an appropriate diagnostic imaging service. The Amendment Determination will enable providers to substitute a PET imaging scan when a preferred Tc-99m based scan under items 61348, 61402, 61421, or 61425 has been requested and is not available due to the supply interruption. These changes will enable medical practitioners to be more responsive and better able to reschedule patients to use PET items as required. The amended PET items will be available on an ongoing basis to allow medical practitioners to provide these services in shorter periods of supply disruption, with the items available for use as soon as a shortage is identified.

The Amendment Determination will also repeal items 61311, 61332, 61365, 61377, 61380, 61418, 61422 (myocardial perfusion studies using PET items), 61337 (bone study with PET items) and 61344 (CT attenuation correction or anatomic localisation items). Stakeholder feedback and utilisation data indicated that the myocardial perfusion studies using PET items were of limited use during previous Tc-99m supply disruptions, the bone study with PET item duplicates other service items, and the CT attenuation correction or anatomic localisation item is obsolete and can be claimed through existing item 61505.

The Government supported and announced this change in the 2022-23 Budget under the *Guaranteeing Medicare – Medical Benefits Schedule new and amended listings* measure, as well as being endorsed by the Medical Services Advisory Committee (MSAC) Executive, at their 29 October 2021 meeting.

This Amendment Determination will commence on 1 November 2022.

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 the existing rights to health and social security and the existing right of equality and non-discrimination by enabling patient access to alternative positron emission tomography (PET) imaging services during radiopharmaceutical supply disruptions of Tc-99m. Amended items 61333, 61336 and 61341 will enable continuity of patient care rather than delayed care by ensuring patients continue to have affordable access to these diagnosis services during supply disruptions.

The repealed items 61311, 61332, 61365, 61377, 61380, 61418, 61422, 61337 and 61344 maintain the existing rights to health, the right to social security and the right of equality and non-discrimination as patients continue to have access to the delivery of alternative services during supply disruptions of Tc-99m under items 61333, 61336 and 61341. According to stakeholder feedback and utilisation data, the myocardial perfusion studies using PET items were of limited use during previous Tc-99m supply disruptions, the bone study with PET

item duplicates other service items, and the CT attenuation correction or anatomic localisation item is obsolete and can be claimed through the existing item 61505.

Conclusion

This instrument is compatible with human rights as it maintains the right to health, the right to social security and the right of equality and non-discrimination, by continuing services during disruptions of supply.

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