

EXPLANATORY STATEMENT

Health Insurance Act 1973

Health Insurance (Section 3C Diagnostic Imaging – Nuclear Medicine Services) Amendment Determination 2020

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 general diagnostic imaging service 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 4AA(1) of the Act.

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 – Nuclear Medicine Services) Amendment Determination 2020* (the Amendment Determination) is to allow patients access to substitute nuclear medicine items under the Medicare Benefits Schedule (MBS) during a disruption in the supply of certain radiopharmaceuticals.

On 14 September 2019, substitute nuclear medicine items were introduced to allow patients continued access to certain nuclear medicine services during a disruption in the supply of radiopharmaceuticals resulting in shortages. Following the introduction of these items, the supply of nuclear medicine isotopes stabilised and as there was no longer a need for these services, the substitute items were suspended on 20 December 2019. The substitute nuclear medicine items are listed in the *Health Insurance (Section 3C Diagnostic Imaging – Nuclear Medicine Services) Determination 2019* (the Principal Determination).

The Amendment Determination will amend the Principal Determination to reinstate the substitute items from 1 December 2020 until 28 February 2021. If the supply of nuclear medicine isotopes stabilises earlier, then this date will be bought forward. Alternatively it can be extended if supply is not stabilised.

The Amendment Determination will also amend existing substitute items (61311 and 61332) and will introduce five new substitute items (61365, 61377, 61380, 61418 and 61422) to align with changes made to cardiac services on 1 August 2020 and 15 September 2020. This will ensure that patients are able to access appropriate nuclear medicine items during the current shortage of nuclear medicine isotopes.

Consultation

The Australasian Association of Nuclear Medicine Specialists (AANMS), the Royal Australian and New Zealand College of Radiologists (RANZCR) and the Australian Diagnostic Imaging Association (ADIA) were consulted in the development of the temporary items. These peak bodies were consulted on in relation to the reinstatement of the substitute nuclear medicine items.

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

The Amendment Determination commences immediately after registration.

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 – Nuclear Medicine Services) Amendment Determination 2020Section 1 – Name

Section 1 provides for the Determination to be referred to as the *Health Insurance (Section 3C Diagnostic Imaging – Nuclear Medicine Services) Amendment Determination 2020*.

Section 2 – Commencement

Section 2 provides that the Determination commences immediately after registration.

Section 3 – Authority

Section 3 provides that the 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 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 Determination has effect according to its terms.

Schedule 1 – Amendments***Health Insurance (Section 3C Diagnostic Imaging – Nuclear Medicine Services) Determination 2019 (the Principal Determination)***

Item 1 inserts a definition of the general medical services table, Modified Monash 3 area, Modified Monash 4 area, Modified Monash 5 area, Modified Monash 6 area and Modified Monash 7 area into section 4 of the Principal Determination.

The definition of a Modified Monash 3 to 7 area has the same meaning given by clause 7.1.1 of the general medical services table. The general medical services table is prescribed under subsection 4(1) of the *Health Insurance Act 1973* (the Act).

A service under new items 61377 and 61380 can only be provided at, or from, a practice located in a Modified Monash 3, 4, 5, 6 or 7 area, and only if a stress echocardiography service is not available in the Modified Monash area where the service is provided.

Item 2 inserts new clauses in relation to the application of the substitute items into Schedule 1 of the Principal Determination. Clauses 1.1.1 and 1.1.2 apply to the application of myocardial perfusion study items 61311, 61332, 61365, 61377, 61380 and 61418. A service under these items can only be provided if the patient displays one or more symptoms of typical or atypical angina, or one or more indications in relation to suggested cardiac ischemia or valvular pathology, or for patients at intermediate to high cardiovascular risk undergoing pre-operative assessment for high-risk surgery. This will ensure that the provision of these services are based

on the clinical risk of the patient, and that the services are not provided inappropriately. The request for a service under these items must identify any symptoms or clinical indications.

Clause 1.1.3 provides that items 61311, 61332, 61365, 61377, 61380 and 61418 can only be provided if the myocardial perfusion study is performed by a person trained in exercise testing and cardiopulmonary resuscitation who is in personal attendance during the procedure, and if a second person who is also trained in exercise testing and cardiopulmonary resuscitation, is located at the diagnostic imaging premise where the procedure is performed and is immediately available to respond at the time the exercise test is performed on the patient.

At least one of these people must be a medical practitioner, and the myocardial perfusion study can only be performed on premises equipped with resuscitation equipment, which includes a defibrillator. This will ensure patient safety during a test that can present significant risk and will maximise the results obtained for the purpose of reporting and subsequent treatment.

Clause 1.1.4 provides restrictions on the myocardial perfusion study items. Subclause 1.1.4(1) provides that item 61311 cannot be provided to a patient who is 17 years old or older, if in the previous 24 months, the patient has had a service provided under item 61332, 61377 or 61380, or a service under cardiac item 61324, 61349, 61357, 61365, 61394, 61398, 61406, 61410, 61414 or 61418.

Subclause 1.1.4(2) provides that item 61332 cannot be provided to a patient who is 17 years old or older, if in the previous 24 months, the patient has had a service provided under item 61311, 61377, 61380 or 61422, or a service under cardiac item 61329, 61345, 61349, 61365, 61410 or 61418.

Subclause 1.1.4(3) provides that item 61365 cannot be provided to a patient if in the previous 12 months, the patient has had a service provided under cardiac item 61349, 61410 or 61418.

Subclause 1.1.4(4) provides that item 61337 cannot be provided to a patient who is 17 years old or older, if in the previous 24 months, the patient has had a service provided under item 61311, 61332, 61380 or 61422, or a service under cardiac item 61329, 61345, 61349, 61365, 61394, 61410, 61414 or 61418.

Subclause 1.1.4(5) provides that item 61380 cannot be provided to a patient who is 17 years old or older, if in the previous 24 months, the patient has had a service provided under item 61311, 61332, 61337 or 61422, or a service under cardiac item 61349, 61365, 61398, 61406, 61410 or 61418.

Subclause 1.1.4(6) provides that item 61418 cannot be provided to a patient if in the previous 12 months, the patient has had a service provided under cardiac item 61349, 61365 or 61410.

Subclause 1.1.4(7) provides that item 61422 cannot be provided to a patient who is 17 years old or older, if in the previous 24 months, the patient has had a service provided under item 61332 or 61380, or a service under cardiac item 61321, 61325, 61329, 61345, 61349, 61365, 61410 or 61418.

Subclause 1.1.4(8) and 1.1.4(9) provides that an attendance service cannot be provided with a myocardial perfusion study service (items 61311, 61332, 61365, 61377, 61380 or 61418) to the same patient on the same day.

The exception to this is if the attendance service is provided after another service and clinical management decisions are made about the patient during the other service, or if the decision to perform the echocardiogram service or myocardial perfusion study service on the same day is made as a result of a clinical assessment of the patient during the attendance service.

Item 3 repeals and replaces the table in Schedule 1 of the Principal Determination to amend two existing substitute items (61311 and 61332) and to list five new substitute items (61365, 61377, 61380, 61418 and 61422)) to align with recent changes made to cardiac services. The new and amended items will mirror existing cardiac items:

- Item 61311 is amended to mirror existing items 61324 and 61357.
- Item 61332 is amended to mirror existing item 61329 and 61345.
- New item 61365 is listed to mirror existing item 61349.
- New item 61377 is listed to mirror existing items 61394 and 61414
- New item 61380 is listed to mirror existing item 61398 and 61406
- New item 61418 is listed to mirror existing item 61410
- New item 61422 is listed to mirror existing item 61321

Item 4 repeals and replaces the table in Schedule 2 of the Principal Determination to provide that the substitute items in Schedule 1 of the Principal Determination will commence on 1 December 2020 and will apply until 28 February 2021.

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 2020*

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 – Nuclear Medicine Services) Amendment Determination 2020* (the Amendment Determination) is to allow patients access to substitute nuclear medicine items under the Medicare Benefits Schedule (MBS) during a disruption in the supply of certain radiopharmaceuticals.

On 14 September 2019, substitute nuclear medicine items were introduced to allow patients continued access to certain nuclear medicine services during a disruption in the supply of radiopharmaceuticals resulting in shortages. Following the introduction of these items, the supply of nuclear medicine isotopes stabilised and as there was no longer a need for these services, the substitute items were suspended on 20 December 2019. The substitute nuclear medicine items are listed in the *Health Insurance (Section 3C Diagnostic Imaging – Nuclear Medicine Services) Determination 2019* (the Principal Determination).

The Amendment Determination will amend the Principal Determination to reinstate the substitute items from 1 December 2020 until 28 February 2021. If the supply of nuclear medicine isotopes stabilises earlier, then this date will be brought forward. Alternatively it can be extended if supply is not stabilised.

The Amendment Determination will also amend existing substitute items (61311 and 61332) and will introduce five new substitute items (61365, 61377, 61380, 61418 and 61422) to align with changes made to cardiac services on 1 August 2020 and 15 September 2020. This will ensure patients are able to access appropriate nuclear medicine items during the current shortage of nuclear medicine isotopes.

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 advances the right to health and the right to social security.

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