#### EXPLANATORY STATEMENT

# Issued by the Authority of the Minister for Health

Health Insurance Act 1973

Health Insurance Legislation Amendment (Section 3C – Cardiac Services) 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 medical services table (the GMST) and the diagnostic imaging services table (the DIST) shall, in specified circumstances and for specified statutory provisions, be treated as if it were specified in one of these tables.

The GMST is set out in the regulations made under subsection 4(1) of the Act. The GMST is currently prescribed in the *Health Insurance (General Medical Services Table) Regulations (No. 2) 2020.* 

The DIST is set out in the regulations made under subsection 4AA(1) of the Act. The DIST is currently prescribed in the *Health Insurance (Diagnostic Imaging Services Table) Regulations (No. 2) 2020.* 

Subsection 33(3) of the *Acts Interpretation Act 1901* 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 Legislation Amendment (Section 3C – Cardiac Services)*Determination 2020 (the Determination) is to amend the *Health Insurance (Section 3C Diagnostic Imaging Services – Cardiac Services)*Determination 2020 (Principal DIST Determination) and the *Health Insurance (Section 3C General Medical Services – Cardiac Services)*Determination 2020 (Principal GMST Determination). The Determination will amend some existing cardiac items to clarify the intent and will list six new items for cardiac services.

In the 2018-19 Mid-Year Economic and Fiscal Outlook (MYEFO) under the *Guaranteeing Medicare – strengthening primary care* measure, the Government agreed to some recommendations made by the clinician-led Medicare Benefits Schedule Review Taskforce (the Taskforce) to cardiac services.

On 1 August 2020, the Principal DIST Determination listed 19 new items for cardiac diagnostic imaging services, and the Principal GMST Determination listed ten new items for cardiac investigation services.

## Amendments made to the Principal DIST Determination

The Determination will amend the Principal DIST Determination to list five new myocardial perfusion study (MPS) items (61394, 61398, 61406, 61410 and 61414). The new items will allow patients to access MPS services where stress echocardiography services are not readily available. The new services will benefit patients who live in rural or remote areas (as defined by

Modified Monash 3 to 7 areas) and who are unable to access a stress echocardiography service as the first line investigation.

The Determination will also amend existing cardiac diagnostic imaging items to clarify that the provision of the service can include planar imaging, as opposed to the requirement that planar imaging must be provided. Co-claiming restrictions against the new items will be added.

# Amendments made to the Principal GMST Determination

The Determination will amend the Principal GMST Determination to list one new item 11735 for continuous electrocardiogram monitoring and to amend existing items to include co-claiming restrictions.

New item 11735 is for continuous electrocardiogram recording of an ambulatory patient for seven days utilising intelligent microprocessor-based monitoring. This service will provide an additional service using this technology, which can record continuously for up to 30 days if required, thereby providing appropriate monitoring and improving patient care.

### Consultation

Consultation was undertaken on the cardiac changes that were recommended by the Taskforce, and announced in the 2018-19 MYEFO under the *Guaranteeing Medicare – strengthening primary care* measure.

The Taskforce engaged expert committees and working groups focusing on specific areas of Medicare. The Cardiac Services Clinical Committee (CSCC) report on changes to cardiac services was released for public comment and further consideration taken based on stakeholder feedback. The CSCC report was then presented to the Taskforce for finalisation and endorsement of the recommendations, before being presented to Government.

Consultation on the changes to the cardiac items which the Determination implements was undertaken with the Australian Diagnostic Imaging Association, the Australian Association of Nuclear Medicine Specialists and nuclear medicine specialists.

Details of the Determination are set out in the Attachment.

The Act specifies no conditions that need to be satisfied before the power to make the Determination may be exercised.

The Determination commences on 15 September 2020.

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

The 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* as set out in the attached Statement of Compatibility with Human Rights.

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

# Details of the Health Insurance Legislation Amendment (Section 3C – Cardiac Services) Determination 2020

## Section 1 – Name

Section 1 provides for the Determination to be referred to as the *Health Insurance Legislation Amendment (Section 3C – Cardiac Services) Determination 2020.* 

## Section 2 – Commencement

Section 2 provides that the Determination commences on 15 September 2020.

# 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 Services – Cardiac Services) Determination 2020 (Principal DIST Determination)

## **Item** [1] – **Subsection** 6(24)

Section 6 of the Principal DIST Determination specifies provisions of the diagnostic imaging services table (DIST) that apply as if items in Schedule 1 of the Principal DIST Determination were specified in the relevant provisions of the DIST.

Item 1 repeals and replaces subsection 6(24) to provide that new items (61394, 61398, 61406, 61410 and 61414) as well as current items (61321, 61324, 61325, 61329, 61345, 61349 and 61357) will be treated as if the items were specified in clause 2.4.1 of the DIST.

Clause 2.4.1 of the DIST provides that nuclear scanning services (other than positron emission tomography, which is covered under clause 2.4.2 of the DIST) are to be performed by a specialist or consultant physician whose name is included in a register, given to the Chief Executive Medicare by the Joint Nuclear Medicine Credentialling and Accreditation Committee (JNMCAC), of participants in the Joint Nuclear Medicine Specialist Credentialling Program of the JNMCAC, or a person acting on behalf of a specialist or consultant physician. The final report is also to be compiled by the specialist or consultant physician who performed the preliminary examination.

## Item [2] – Division 1.1 of Schedule 1 (subclause 1.1.1(3))

Item 2 repeals and substitutes subclause 1.1.1(3) to amend subparagraph (c)(iv) to clarify that an indication to access a service under items 55141, 55143, 55145 or 55146 can include either an

assessment by a specialist or consultant physician where it indicates that the patient has potential non-coronary artery disease and where the stress echocardiography service is likely to assist the diagnosis (as per subparagraph (c)(iv) in the Determination), or if an assessment, which can be undertaken by a medical practitioner, indicates that the patient has undue exertional dyspnoea of uncertain aetiology (as per subparagraph (c)(v) in the Determination).

Subclause 1.1.1(3) provides that a service provided under item 55141, 55143, 55145 or 55146 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 change will ensure that the assessment of the patient for these indications is undertaken appropriately, and provides a delineation between the assessment by a medical practitioner or a specialist or consultant physician.

## Item [3] – Division 1.1 of Schedule 1 (below clause 1.1.2)

Item 3 repeals and replaces the table with a new table in Division 1.1 of Schedule 1. The new table includes amended item descriptors for items 55126, 55127, 55128, 55129, 55132, 55133, 55134, 55137, 55141, 55143, 55145 and 55146 to provide that these services cannot be provided in association with a service under Subgroup 1 (except item 55054) or Subgroup 3 of the DIST. This is an administrative change to clarify this restriction, which applied to ceased echocardiographic items (55113, 55114, 55115, 55116 and 55117) which the current items replaced on 1 August 2020.

Item 55132 is also amended to remove the requirement that the service can only be requested by a specialist or consultant physician. Item 55132 is for a serial real-time echocardiographic examination for patients aged under 17 years, or patients of any age with complex congenital heart disease. Removing this restriction will enable medical practitioners to be able to request this service based on their clinical judgement, and will expand patient access, particularly for patients who are unable to see a specialist or consultant physician.

## Item [4] – Division 1.2 of Schedule 1 (subclause 1.2.1(1))

Item 4 repeals and replaces subclause 1.2.1(1) to insert new items 61394, 61398, 61406, 61410 and 61414, and to clarify that under subparagraph (c)(vii), the indication is for a patient with congenital heart lesions who have undergone surgery, where ischemia is considered possible, as opposed to the reversal of ischemia is considered possible.

Subclause 1.2.1(1) provides that specific myocardial perfusion study (MPS) services can only be claimed 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 change will ensure that services provided under the new items will be performed based on the clinical need of the patient.

## Item [5] – Division 1.2 of Schedule 1 (subclause 1.2.1(2))

Item 5 repeals and replaces subclause 1.2.1(2) to insert new items 61394, 61398, 61406, 61410 and 61414. Subclause 1.2.1(2) provides that the request for the provision of a service must identify the relevant symptom/s or indication/s of the patient, which are outlined in subclause 1.2.1(1) of the Principal DIST Determination.

# Item [6] – Division 1.2 of Schedule 1 (subclause 1.2.1(3))

Item 6 amends subclause 1.2.1(3) to insert new items 61394, 61398, 61406, 61410 and 61414. Subclause 1.2.1(3) provides that a service can only be claimed if the diagnostic imaging procedure is performed by a person trained in cardiopulmonary resuscitation who is in personal attendance during the procedure, and if a second person who is also trained in cardiopulmonary resuscitation as well as exercise testing, 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 diagnostic imaging procedure can only be performed on premises equipped with resuscitation equipment, which includes a defibrillator. This change will ensure patient safety during a test claimed under the new services and will maximise the results obtained for reporting and subsequent treatment.

## Item [7] – Division 1.2 of Schedule 1 (subclause 1.2.1(4))

Item 7 amends subclause 1.2.1(4) to insert new nuclear imaging service items 61394, 61398, 61406, 61410 and 61414. Subclause 1.2.1(4) provides that an attendance service cannot be provided on the same day as the nuclear imaging service, except if the attendance service is provided after the nuclear imaging service where clinical management decisions are made, or if the decision to perform the nuclear imaging service on the same day was made during the attendance service subject to clinical assessment.

# Item [8] – Division 1.2 of Schedule 1 (subclause 1.2.2(1))

Item 8 repeals and replaces subclause 1.2.2(1) to include new items 61394, 61398, 61406 and 61414. Subclause 1.2.2(1) provides that a service can only be provided once every two years if the patient is 17 years old or older.

# Item [9] – Division 1.2 of Schedule 1 (below clause 1.2.2)

Item 9 repeals and replaces the table with a new table in Division 1.2 of Schedule 1. The new table amends current items 61321, 61324, 61325, 61329, 61345, 61349 and 61357, and inserts five new myocardial perfusion studies (MPS) items 61394, 61398, 61406, 61410 and 61414.

The item descriptor of current items 61321 to 61357 have been amended to clarify that the provision of the service can include planar imaging, as opposed to the requirement that planar imaging must be provided. Additional co-claim restriction requirements have also been applied as follows:

- Items 61321 and 61325 cannot be provided with new items 61398 or 61406.
- Items 61324, 61329, 61345 and 61357 cannot be provided with new items 61394, 61398, 61406 or 61414.
- Item 61349 can be provided if in the previous 24 months, the patient has had a service provided under new items 61394, 61398, 61406 or 61414 and has undergone a revascularisation procedure.

The table lists the following five new MPS items which can only be provided if a stress echocardiography service is unable to be provided in the area, and if the practice is located in a Modified Monash 3 to 7 area:

- Item 61394 is for a single stress MPS to investigate cardiac ischemia. This service can only be requested by a specialist or consultant physician.
- Item 61398 is for a combined rest and stress MPS study to investigate cardiac ischemia. This service can only be requested by a medical practitioner (other than a specialist or consultant physician).

- Item 61406 is for a combined rest and stress MPS study, to allow the comparison of previous myocardial injury (single rest) with evolving myocardial ischemia. This service can only be requested by a specialist or consultant physician.
- Item 61410 is for a repeat combined rest and stress MPS study, which can only be provided once a year to patients with evolving symptoms who are not adequately controlled with optimal medical therapy, following a revascularisation procedure. This service can be requested by any medical practitioner.
- Item 61414 is for a single stress MPS to investigate cardiac ischemia. This service can only be requested by a medical practitioner (other than a specialist or consultant physician).

Health Insurance (Section 3C General Medical Services – Cardiac Services) Determination 2020 (Principal GMST Determination)

# **Item** [10] – **Subsection** 6(2)

Section 6 of the Principal GMST Determination specifies provisions of the general medical services table (GMST) that apply as if items in Schedule 1 of the Principal GMST Determination were specified in the relevant provisions of the general medical services table.

Item 10 repeals and replaces subsection 6(2) to provide that new item 11735, as well as items 11704, 11707, 11714, 11716, 11717, 11723, 11729 and 11730 will be treated as if the items were specified in clause 1.2.11 of the GMST. Item 11705 is also removed as this service can only be provided by a specialist or consultant physician. Clause 1.2.11 prescribes a list of items that can be performed on behalf of a medical practitioner by a non-medical practitioner, providing they are employed by the medical practitioner or perform the service under the supervision of a medical practitioner in accordance with accepted medical practice.

## Item [11] – Section 7 (below the heading)

Section 7 of the Principal GMST Determination provides the condition of how items are to be investigated. Item 11 repeals and replaces section 7 to provide how new item 11735, as well as items 11716, 11717, 11723 and 11729 are to be investigated.

Subsection 7(1) provides that a service to which an item applies can be requested by a requesting practitioner or referred. Subsection 7(2) specifies a service is taken to be referred if the specialist or consultant physician who renders the service manages the ongoing care of the patient, or determines the need for a cardiac investigation that has not otherwise been scheduled, or performs a scheduled test but also provides an attendance where clinical management decisions are discussed with the patient. Services in all other circumstances are considered to be requested, per subsection 7(3).

## Item [12] – Subsection 8(1) (including the heading)

Section 8 of the Principal GMST Determination provides restrictions on the provision of services. Item 12 repeals and replaces subsection 8(1) (including the heading) to provide that new item 11735, as well as items 11704, 11707, 11714, 11716, 11717 and 11723 do not apply where the patient is an "admitted patient" of a hospital.

# **Item [13] – Subsection 8(10) (including the heading)**

Item 13 repeals and replaces subsection 8(10) (including the heading) to provide that where new item 11735, as well as items 11716, 11717, 11723 and 11729 are requested, the service does not

apply if the medical practitioner has performed a service to which an attendance applies on the same day.

## Item [14] – Schedule 1 (below the heading)

Item 14 repeals and replaces the table with a new table in Schedule 1. The new table amends current items to include co-claiming restrictions and inserts one new item 11735 for continuous electrocardiogram (ECG) monitoring.

The item descriptor of current items 11704, 11705, 11707, 11714, 11716, 11717 and 11723 is amended to provide that these services cannot be provided in association with sleep study services under items 12203, 12204, 12205, 12207, 12208, 12210, 12213, 12215, 12217 or 12250. The item descriptor of items 11729 and 11730 is amended to include a restriction that these services cannot be provided if a service under new cardiac diagnostic imaging items 61349, 61398, 61406, 61410 or 61414 was performed within 24 months. Co-claiming restrictions have also been applied to current items 11716, 11717, 11723 and 11735 to align with best clinical practice.

New item 11735 is for continuous ECG recording of ambulatory patients for seven days, to investigate abnormal rhythms, in particular when episodes are infrequent but significant. This service will be automated, which would remove inaccurate activation by patients at the time of symptom onset, but still allow activation if the patient is aware of symptoms.

# Statement of Compatibility with Human Rights

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

Health Insurance Legislation Amendment (Section 3C – Cardiac Services) 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* 

### **Overview of the Determination**

The purpose of the Health Insurance Legislation Amendment (Section 3C – Cardiac Services)

Determination 2020 (the Determination) is to amend the Health Insurance (Section 3C

Diagnostic Imaging Services – Cardiac Services) Determination 2020 (Principal DIST

Determination) and the Health Insurance (Section 3C General Medical Services – Cardiac

Services) Determination 2020 (Principal GMST Determination). The Determination will amend some existing cardiac items to clarify the intent and will list six new items for cardiac services.

In the 2018-19 Mid-Year Economic and Fiscal Outlook (MYEFO) under the *Guaranteeing Medicare – strengthening primary care* measure, the Government agreed to some recommendations made by the clinician-led Medicare Benefits Schedule Review Taskforce (the Taskforce) to cardiac services.

On 1 August 2020, the Principal DIST Determination listed 19 new items for cardiac diagnostic imaging services, and the Principal GMST Determination listed ten new items for cardiac investigation services.

# Amendments made to the Principal DIST Determination

The Determination will amend the Principal DIST Determination to list five new myocardial perfusion study (MPS) items (61394, 61398, 61406, 61410 and 61414). The new items will allow patients to access MPS services where stress echocardiography services are not readily available. The new services will benefit patients who live in rural or remote areas (as defined by Modified Monash 3 to 7 areas) and who are unable to access a stress echocardiography service as the first line investigation.

The Determination will also amend existing cardiac diagnostic imaging items to clarify that the provision of the service can include planar imaging, as opposed to the requirement that planar imaging must be provided. Co-claiming restrictions against the new items will be added.

## Amendments made to the Principal GMST Determination

The Determination will amend the Principal GMST Determination to list one new item 11735 for continuous electrocardiogram monitoring and to amend existing items to include co-claiming restrictions.

New item 11735 is for continuous electrocardiogram recording of an ambulatory patient for seven days utilising intelligent microprocessor-based monitoring. This service will provide an additional service using this technology, which can record continuously for up to 30 days if required, thereby providing appropriate monitoring and improving patient care.

# **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 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 community.

### **Analysis**

This instrument advances rights to health and social security by listing new cardiac items for the provision of myocardial perfusion study services in rural and remote areas for patients who are unable to access a stress echocardiography service. The instrument lists a new item for the continuous electrocardiogram recording which utilises intelligent microprocessor based monitoring. These new items will expand patient access to cardiac services. The instrument also amends current cardiac items to apply appropriate co-claiming restrictions and to clarify the intent of the services.

#### Conclusion

This instrument is compatible with human rights because it maintains existing arrangements and the protection of human rights.

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