

## EXPLANATORY STATEMENT

### *Health Insurance Act 1973*

#### *Health Insurance (Section 3C Diagnostic Imaging Services – Cardiac MRI for Myocarditis) Determination 2024*

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*.

#### **Purpose**

The purpose of the *Health Insurance (Section 3C Diagnostic Imaging Services – Cardiac MRI for Myocarditis) Determination 2024* (the Determination) is to insert new magnetic resonance imaging (MRI) item 63390 for the diagnosis of myocarditis in patients with:

- acute onset (less than 3 months duration) of heart failure caused by suspected myocarditis, which would otherwise require endomyocardial biopsy to confirm diagnosis; or
- unexplained arrhythmia caused by suspected myocarditis, which would otherwise require endomyocardial biopsy to confirm diagnosis; or
- suspected drug-induced myocarditis, where other tests have been performed but are inconclusive.

Item 63390 will replace the current temporary Medicare Benefits Schedule item 63399 that is listed in the *Health Insurance (Section 3C Diagnostic Imaging – Cardiac MRI for Myocarditis) Determination 2021* to aid in diagnosing myocarditis associated with mRNA COVID-19 vaccination. A repealing instrument will be registered which will cease temporary item 63399 from 1 January 2025.

Myocarditis is an inflammatory condition of the heart muscle which may be triggered by infection and autoimmune conditions including drug reactions. Acute myocarditis is the most common type of myocarditis (comprising two thirds of all cases) and has a short interval between when symptoms start and diagnosis (usually less than one month). This change will continue to support the diagnosis of vaccine-induced myocarditis, including cases associated with COVID-19, and assist adverse events reporting to the Therapeutic Goods Administration. This change will also broaden patient access to MRI for the diagnosis of myocarditis by removing the limitation on the patient having received an mRNA COVID-19 vaccine, or the symptoms having materialised within 21 days of receiving the vaccine, as an eligibility condition. This will mean fewer patients needing to receive an invasive endomyocardial biopsy procedure to diagnosis myocarditis.

Approval to list new item 63390 was granted by the Minister for Health and Aged Care through the authority to approve certain Medical Services Advisory Committee

recommendations outside of a budget process. This authority was granted through the 2024-25 Budget under the *Strengthening Medicare* measure.

### **Consultation**

The Department of Health and Aged Care consulted with the following stakeholders in relation to this change:

- Australian & New Zealand Society of Cardiac & Thoracic Surgeons
- Australian and New Zealand Society for Vascular Surgery
- Australian College of Rural and Remote Medicine
- Australian Diagnostic Imaging Association
- Australian Medical Association
- Australian Society of Medical Imaging and Radiation Therapy
- Cardiac Society of Australia and New Zealand
- Consumer Health Forum
- Heart Foundation
- Royal Australasian College of Physicians
- Royal Australasian College of Surgeons
- Royal Australian and New Zealand College of Radiologists
- Royal Australian College of General Practitioners
- Australian National Chapter of the International Society for Magnetic Resonance Radiographers and Technologists

All stakeholders supported the introduction of a permanent MRI item for the diagnosis of myocarditis in this patient population, but some were not supportive of the schedule fee. The schedule fee has since been increased in response to stakeholder feedback.

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

The Determination commences on 1 January 2025.

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

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

## ATTACHMENT

**Details of the *Health Insurance (Section 3C Diagnostic Imaging Services – Cardiac MRI for Myocarditis) Determination 2024***Section 1 – Name

Section 1 provides for the Determination to be referred to as the *Health Insurance (Section 3C Diagnostic Imaging Services – Cardiac MRI for Myocarditis) Determination 2024* (the Determination).

Section 2 – Commencement

Section 2 provides for the Determination to commence on 1 January 2025.

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 diagnostic imaging service and as if there were an item specified in the diagnostic imaging services table for the service.

Section 6 – Application of provisions of the diagnostic imaging services table

Subsection 6(1) provides the requirements for services provided under item 63390, stating that a Medicare benefit is only available for a service provided under the item if:

- the service is performed in a permissible circumstance as described in clause 2.5.3 of the diagnostic imaging services table;
- the service is provided by a person who meets the requirements as described in clause 2.5.4 of the diagnostic imaging services table; and
- the service is performed using equipment as described in clause 2.5.6 of the diagnostic imaging services table.

Subsection 6(2) provides that item 63390 will be treated as if it was specified in column 1 of item 1 and 2 of table 2.5.4 of the diagnostic imaging services table. Table 2.5.4 provides the meaning of ‘eligible provider’ for an MRI service under item 63300.

### Section 7 – Application of contrast

Section 7 provides that where a service to which an item in the Schedule applies is performed using a contrast agent, the fee specified in that item applies in addition to the schedule fee in item 63491 of the diagnostic imaging services table.

### Schedule 1 – Relevant services

Schedule 1 specifies the service and associated fee for item 63390.

## 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 – Cardiac MRI for Myocarditis) Determination 2024*

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 – Cardiac MRI for Myocarditis) Determination 2024* (the Determination) is to insert new magnetic resonance imaging (MRI) item 63390 for the diagnosis of myocarditis in patients with:

- acute onset (less than 3 months duration) of heart failure caused by suspected myocarditis, which would otherwise require endomyocardial biopsy to confirm diagnosis; or
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Myocarditis is an inflammatory condition of the heart muscle which may be triggered by infection and autoimmune conditions including drug reactions. Acute myocarditis is the most common type of myocarditis (comprising two thirds of all cases) and has a short interval between when symptoms start and diagnosis (usually less than one month). This change will continue to support the diagnosis of vaccine-induced myocarditis, including cases associated with COVID-19, and assist adverse events reporting to the Therapeutic Goods Administration. This change will also broaden patient access to MRI for the diagnosis of myocarditis by removing the limitation on the patient having received an mRNA COVID-19 vaccine, or the symptoms having materialised within 21 days of receiving the vaccine, as an eligibility condition. This will mean fewer patients needing to receive an invasive endomyocardial biopsy procedure to diagnosis myocarditis.

### 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 increases the rights to health and social security and maintains the right of equality and non-discrimination by continuing to provide access to Medicare benefits for the diagnosis (by MRI) of myocarditis in patients with particular symptoms without the limitation on the patient having received an mRNA COVID-19 vaccine, or the symptoms having materialised within 21 days of receiving the vaccine, as an eligibility condition.

#### **Conclusion**

This instrument is compatible with human rights as it increase the right to health and the right to social security and maintains the right of equality and non-discrimination.

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