

EXPLANATORY STATEMENT

Health Insurance Act 1973

Health Insurance (Section 3C Diagnostic Imaging – Cardiac MRI for Myocarditis) Determination 2021

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 subsection 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 – Cardiac MRI for Myocarditis) Determination 2021* (the Determination) is to list a new temporary item for cardiac magnetic resonance imaging (MRI) to diagnose myocarditis associated with mRNA COVID-19 vaccination. The item is for use in circumstances where myocarditis cannot be definitively diagnosed using conventional imaging and other diagnostic tests. This Determination commences on 1 January 2022.

Myocarditis refers to inflammation of the heart muscle. It is a rare side effect that can occur after vaccination with the mRNA COVID-19 vaccines Comirnaty (Pfizer) and Spikevax (Moderna). An increased risk of myocarditis has been observed in people who have received these vaccines compared to unvaccinated people. Severe instances of myocarditis may lead to heart failure or even death. It is most commonly reported in males under the age of 30 years, with a higher incidence after the second vaccine dose. In Australia, myocarditis is reported in approximately 1 out of every 100,000 people, across all age groups, after receiving a mRNA COVID-19 vaccine. The incidence is much higher in individuals under the age of 19 years.

In October 2021, the Medical Services Advisory Committee (MSAC) Executive recommended introducing a new temporary item to support the diagnosis of myocarditis associated with mRNA COVID-19 vaccination using cardiac MRI. The MSAC Executive supported the item being available temporarily to allow for a full health technology assessment on the use of cardiac MRI in diagnosing myocarditis more broadly to be considered.

Accurate diagnosis of myocarditis associated with mRNA COVID-19 vaccines will impact the ongoing management of Australia's COVID-19 vaccination program. This new item will provide patients with access to this service without high out-of-pocket costs if it is being accessed outside of the public hospital system.

Consultation

The introduction of a new cardiac MRI service to identify myocarditis associated with mRNA COVID-19 vaccination is supported by the Cardiac Society of Australia and

New Zealand (CSANZ), the Australian and New Zealand Working Group for Cardiovascular MRI (ANZCMR) and the Chief Medical Officer.

Details of the Determination are set out in the Attachment.

The Determination commences on 1 January 2022.

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 – Cardiac MRI for Myocarditis) Determination 2021

Section 1 – Name

Section 1 provides for the Determination to be referred to as the *Health Insurance (Section 3C Diagnostic Imaging – Cardiac MRI for Myocarditis) Determination 2021*.

Section 2 – Commencement

Section 2 provides that the Determination commences on 1 January 2022.

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

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

Section 6 specifies provisions of the diagnostic imaging services table that apply as if item 63399 was specified in the relevant provision in the diagnostic imaging services table.

Subsection 6(1) of the Determination provides that item 63399 will be treated as if it was specified in subclauses 2.5.3 (permissible circumstances), 2.5.4 (eligible provider), 2.5.5 (eligible equipment) and 2.5.6 (partial eligible equipment) of the diagnostic imaging services table.

Subsection 6(2) of the Determination provides that clause 2.5.4 of the diagnostic imaging services table, which describes **eligible provider** for the purposes of MRI services, will apply to item 63399 as if the item was specified in column 1 for item 1 and item 2 of table 2.5.4.

Accordingly, an eligible provider for the purposes of item 63399 includes:

- a person who is a specialist in diagnostic radiology and satisfies the Chief Executive Medicare that the specialist is a participant in the Royal Australian and New Zealand College of Radiologists' Quality and Accreditation Program; and
- a person who is a specialist in diagnostic radiology or a consultant physician and is recognised by the Conjoint Committee for Certification in Cardiac MRI.

Section 7 – Application of contrast

Section 7 specifies the schedule fee in item 63491 will apply in addition to the schedule fee for item 63399, where a service to which item 63399 applies is performed using contrast.

Schedule – Relevant services

The Schedule specifies the service and the associated fee for item 63399.

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 – Cardiac MRI for Myocarditis) Determination 2021

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

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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 to be understood as 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 advances the right to health, the right to social security and the right of equality and non-discrimination by giving patients access to cardiac MRI services for the diagnosis of myocarditis associated with a mRNA COVID-19 vaccination in circumstances where it cannot be definitively diagnosed using conventional imaging and other diagnostic tests.

Conclusion

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

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