EXPLANATORY STATEMENT

Issued by the Authority of the Minister for Health

Health Insurance Act 1973

Health Insurance (Poly Implant Prosthese MRI) 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 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(1) of the Act. The most recent version of the regulations is the *Health Insurance (Diagnostic Imaging Services Table) Regulations 2019.* This version will be remade on 1 May 2020 by the *Health Insurance (Diagnostic Imaging Services Table) Regulations (No. 1) 2020.*

Purpose

The *Health Insurance (Poly Implant Prosthese MRI) Determination 2020* (the Determination) will remake the *Health Insurance (Poly Implant Prosthese MRI) Determination 2012.*

In April 2010, the Therapeutic Goods Administration (TGA) recalled all unused Poly Implant Prosthese implants (PIP implants), and these implants were withdrawn from the Australian market, subject to the detection of deficiencies in the manufacturing process for the implants.

The Medical Services Advisory Committee (MSAC) recommended that the optimum imaging modality to determine whether there is any need for surgical intervention to remove the implant was by Magnetic Resonance Imaging (MRI). Subject to MSAC's recommendations, in March 2012, six MRI items were introduced for patients who have, or are suspected of having, breast implants manufactured by PIP.

The Determination will enable patients who have, or are suspected of having, breast implants manufactured by PIP, to continue to access the six MRI services.

The Determination will also amend the restriction for the provision of services from 12 months to 24 months, for two items where the request for the service indicates that the patient is asymptomatic for implant rupture (63501 and 63502).

The clinician-led Medicare Benefits Schedule (MBS) Review Taskforce (the MBS Review Taskforce) recommended that a limit of one service per 24 months would be sufficient for the monitoring of implant progress. It would more closely align with the level of monitoring recommended by the Food and Drug Administration in the United States.

This change was announced by Government in the 2019-20 Budget under the *Guaranteeing Medicare – improved patient access to diagnostic imaging* measure.

Consultation
Consultation was not undertaken on the remake of this Determination as it is administrative in nature. Patients who have or were suspected of having PIP implants will continue to be able to access Medicare rebatable MRI services to assess the integrity of their implant.

Consultation was undertaken on the changes to diagnostic imaging services that were recommended by the MBS Review Taskforce, and announced in the 2019-20 Budget under the *Guaranteeing Medicare – improved patient access to diagnostic imaging* measure.

The MBS Review is conducted by expert committees and working groups focusing on specific areas of the MBS. The Taskforce endorsed reports were released for public comment prior to finalisation of the recommendations to the Government. This was undertaken through the public consultation process during consideration by the Taskforce.

Details of the Determination are set out in the Attachment.

The Determination is a legislative instrument for the purposes of the *Legislation Act 2003*. The Act specifies no conditions that need to be satisfied before the power to make the Determination may be exercised.

The Determination commences on 1 May 2020.

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*

ATTACHMENT

Details of the *Health Insurance (Poly Implant Prosthese MRI) Determination 2020*

Section 1 – Name

Section 1 provides for the Determination to be referred to as the *Health Insurance (Poly Implant Prosthese MRI) Determination 2020*.

Section 2 – Commencement

Section 2 provides that the Determination commences on 1 May 2020.

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.

A key term is ‘relevant provisions’ which means all provisions relating to professional or medical services in the Act or regulations made under the Act, or the *National Health Act 1953* or regulations made under that Act, other than clause 1.2.21 of the Table. That clause provides for the ‘multiple services rule, a reduction in fees for diagnostic imaging services where a practitioner provides a patient with multiple services on the same day, for example where a practitioner provides a patient with:

(a) two or more diagnostic imaging services on the same day;

(b) at least one R-type diagnostic imaging service and one consultation service on the same day; or

(c) at least one R-type diagnostic imaging service and one non-consultation service on the same day.

The exclusion of the services in the Determination from the definition of ‘relevant provisions’ means that they will not be taken account of in the operation of the ‘multiple services rule’.

Another key term is 'relevant service' which means a health service specified in the Schedule to the Determination. There are six such relevant services in the Schedule to the Determination.

The term ‘remote location’ is defined as a place within Australia that is over 30 kilometres by road from either a either a hospital that provides radiology or computed tomography (CT) services under the direction of a specialist radiologist, or a free standing radiology or CT facility under the direction of a specialist radiologist. This term is used in section 7 of the Determination.

Subsection 4(2) provides that a reference in the Determination to a provision of an Act or regulations is a reference to that provision as in force from time to time.

Section 5 – Treatment of relevant services

Subsection 5(1) provides that a relevant service specified in Part 1 of the Schedule to the Determination shall be treated as if:

> (a) it were both a professional service and a medical service for the purposes of the provisions of the Act, the *National Health Act 1953* and regulations made under each Act that make provision for medical services or professional services; and
>
> (b) there were an item in the Table that related to the service and specified a fee in respect of that service, being the fee specified in the Schedule to the Determination in relation to the service.

Part 1 of the Schedule contains four services for MRI scans of patients who have or are suspected of having PIP implants (PIP MRI scans).

Subsection 5(2) provides that a relevant service specified in Part 2 of the Schedule to the Determination shall be treated as if:

> (a) it were both a professional service and a medical service for the purposes of the provisions of the Act, the *National Health Act 1953* and regulations made under each Act that make provision for medical services or professional services; and
>
> (b) there were an item in the Table that related to the service and specified a fee in respect of that service, being the fee specified in the Schedule to the Determination in relation to the service.

Part 2 of the Schedule contains two 'modifier' services, which allow for the payment of additional Medicare benefit where a PIP MRI scan is provided using intravenous or intra muscular sedation, or under anaesthesia. These services recognise the additional cost or complexity or providing a PIP MRI scan on a patient under sedation.

Section 6 – Specification of relevant services

Subsection 6(1) applies paragraph 1.2.19 of the Table to the services in the Determination. Clause 1.2.19 creates a 'bulk billing incentive' for diagnostic imaging services, which provides for an increase in Medicare benefit where the service is provided out of hospital and is bulk-billed.

Subsection 6(2) applies clause 2.5.7 of the Table to the services in the Determination. Clause 2.5.7 provides that a 'scan' means a minimum of three sequences.

Section 7 – Supervision and reporting of relevant services

Section 7 applies requirements for the supervision and reporting of PIP MRI scan items.

Section 7 provides that items in Part 1 and Part 2 of the Schedule will only apply to a service provided in one of two circumstances, being:

(a) if the service is professionally supervised by a diagnostic radiology specialist who is available to monitor the quality and conduct of the examination and, if necessary, to personally attend on the patient. The service must also be reported on by a diagnostic radiology specialist; or

(b) if the service is performed in an emergency or, as a result of medical necessity, in a 'remote location'.

Section 8 – Requests for relevant services

Subsection 8(1) provides that an item in Part 1 and Part 2 of the Schedule will only apply following a request by a medical practitioner.

Subsection 8(2) provides that the request must be in writing and must specify that the patient has or is suspected of having a PIP implant, and whether the patient shows symptoms indicating that the implant has or may have ruptured.

Section 9 - Limitation on number of services

Section 9 provides that the services described in items 63501 and 63502 do not apply where the patient has received either of the items in the previous 24 months. Items 63501 and 63502 are for use where a patient does not display symptoms of implant rupture.

There is no restriction on the number of scans that a patient displaying symptoms of implant rupture may receive under the Determination.

Section 10 – modifying items

Item 63498 and 63499 in Part 2 of the Schedule apply where a PIP MRI scan is provided to a patient using intravenous or intramuscular sedation, or anaesthesia, respectively. The items may only be claimed where a PIP MRI scan in Part 1 of the Determination is provided to the patient.

Subsection 10(1) provides that subject to the section, the fee for item 63498 or 63499 applies in addition to the fee for the associated PIP MRI scan item.

Subsection 10(2) limits item 63498 to being claimed only once in respect of the same patient on the same day.

Subsection 10(3) limits item 63499 to being claimed only once in respect of the same patient on the same day.

Subsection 10(4) prevents items 63498 and 64499 from both being claimed in respect of the same patient on the same day.

Schedule – Relevant services

The Schedule sets out the relevant services and assigns to each relevant service the applicable item number, item descriptor and fee.

Items 63501 and 63502 in Part 1 of the Schedule apply where the request for the service indicates that the patient is asymptomatic for implant rupture. Items 63504 and 63505 apply where the request indicates that the patient displays symptoms of implant rupture.

Items 63498 and 63499 in Part 2 of the Schedule apply where a patient is provided with a service in Part 1 of the Schedule and sedation or anaesthesia are used.

Statement of Compatibility with Human Rights

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

Health Insurance (Poly Implant Prosthese MRI) 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 *Health Insurance (Poly Implant Prosthese MRI) Determination 2020* (the Determination) will remake the *Health Insurance (Poly Implant Prosthese MRI) Determination 2012.* The Determination will enable patients who have, or are suspected of having, breast implants manufactured by Poly Implant Prosthese (PIP implants) to continue to access six Medicare-eligible Magnetic Resonance Imaging (MRI) services.

The Determination will also amend the restriction for the provision of services from 12 months to 24 months, for two items where the request for the service indicates that the patient is asymptomatic for implant rupture (63501 and 63502).

The clinician-led Medicare Benefits Schedule (MBS) Review Taskforce (the MBS Review Taskforce) recommended that a limit of one service per 24 months would be sufficient for the monitoring of implant progress. It would more closely align with the level of monitoring recommended by the Food and Drug Administration in the United States.

This change was announced by Government in the 2019-20 Budget under the *Guaranteeing Medicare – improved patient access to diagnostic imaging* measure.

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 maintains rights to health and social security by ensuring access to publicly subsidised health services, which are clinically effective and cost-effective.

Conclusion

This instrument is compatible with human rights as it maintains the right to health and the right to social security.

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