

## EXPLANATORY STATEMENT

Issued by the Authority of the Minister for Health

*Health Insurance Act 1973*

*Health Insurance (Section 3C General Medical Services – Extracorporeal Photopheresis) 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 medical 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 4(1) of the Act. The most recent version of the regulations is the *Health Insurance (General Medical Services Table) Regulations (No. 2) 2020*.

### **Purpose**

The purpose of the *Health Insurance (Section 3C General Medical Services – Extracorporeal Photopheresis) Determination 2020* (the Determination) is to list two new Medicare Benefits Schedule (MBS) items (14247 and 14249) for the treatment of cutaneous T-cell lymphoma (CTCL) with extracorporeal photopheresis (ECP).

CTCL is a rare type of lymphoma characterised by the accumulation of malignant T-cells in the skin resulting in raised, rash-like or itchy patches of skin, skin lumps or ulcers and swollen lymph nodes.

An ECP service is indicated for the management of CTCL in patients who have experienced disease progression or unacceptable toxicity on other systemic treatments for CTCL. It is an apheresis-based immunomodulatory therapy performed via intravenous access, comprising three stages: leukapheresis, photoactivation and reinfusion. Blood is passed through multiple cycles of leukapheresis.

The Determination will list two new MBS items for ECP for the initial treatment for CTCL (item 14247) and the continuing treatment for CTCL (item 14249), for patients who are 18 years old or older. These ECP services are to be delivered by using an integrated, closed extracorporeal photopheresis system, and are to be provided in combination with Pharmaceutical Benefits Scheme subsidised methoxsalen (a substance used as part of the ECP service).

Items 14247 and 14249 can only be provided once per treatment cycle, regardless of the number of consecutive days over which a cycle is performed. This limit would prevent inappropriate claiming, for example, double claiming if treatment is received over two days with an overnight stay. Services under both items are to be administered under the supervision of a specialist or consultant physician in the speciality of haematology.

This proposal was supported by the Medical Services Advisory Committee (MSAC) in April 2020 (MSAC application 1420.1).

**Consultation**

MSAC reviews new or existing medical services or technology, and the circumstances under which public funding should be supported through listing on the MBS. This includes the listing of new items, or amendments to existing items on the MBS.

As part of the MSAC process, consultation was undertaken with key stakeholders, clinical experts and providers, and consumer health representatives.

Details of the Determination are set out in the Attachment.

The Determination commences on 1 November 2020.

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 General Medical Services – Extracorporeal Photopheresis) Determination 2020**

Section 1 – Name

Section 1 provides for the Determination to be referred to as the *Health Insurance (Section 3C General Medical Services – Extracorporeal Photopheresis) Determination 2020*.

Section 2 – Commencement

Section 2 provides that the Determination commences on 1 November 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.

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

Section 6 – Application of provisions of the general medical services table

Section 6 specifies provisions of the general medical services table that apply as if items 14247 and 14249 in the Determination was specified in the relevant provision in the general medical services table.

Subsection 6(1) of the Determination provides that items 14247 and 14249 will be treated as if they were specified in clause 1.2.6 of the general medical services table. Clause 1.2.6 provides that medical practitioners must personally attend the service which must be performed on a single occasion.

Subsection 6(2) of the Determination provides that items 14247 and 14249 will be treated as if they were specified in clause 1.2.7 of the general medical services table. Clause 1.2.7 provides that medical practitioners must personally attend the service. This applies regardless if the medical practitioner, or a person on behalf of the medical practitioner, performs the service.

Subsection 6(3) of the Determination provides that items 14247 and 14249 will be treated as if they were specified in clause 1.2.9 of the general medical services table. Clause 1.2.9 provides circumstances and purposes where a service cannot be rendered.

Subsection 6(4) of the Determination provides that items 14247 and 14249 will be treated as if they were specified in clause 1.2.10 of the general medical services table. Clause 1.2.10 provides that a service cannot be provided at the same time, or in connection with, the harvesting, storage, in vitro processing or injection of non-haematopoietic stem cells.

Subsection 6(5) of the Determination provides that items 14247 and 14249 will be treated as if they were specified in clause 5.1.1 of the general medical services table. Clause 5.1.1 provides that a service, provided in an item in Group T1, does not apply if the service is provided at the same time as, or in connection with, the provision of a pain pump for post- surgical pain management.

#### Schedule 1 – Relevant services

The Schedule specifies the service and the associated fee for items 14247 and 14249.

## Statement of Compatibility with Human Rights

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

*Health Insurance (Section 3C General Medical Services – Extracorporeal Photopheresis) 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 General Medical Services – Extracorporeal Photopheresis) Determination 2020* (the Determination) is to list two new Medicare Benefits Schedule (MBS) items (14247 and 14249) for the treatment of cutaneous T-cell lymphoma (CTCL) with extracorporeal photopheresis (ECP).

CTCL is a rare type of lymphoma characterised by the accumulation of malignant T-cells in the skin resulting in raised, rash-like or itchy patches of skin, skin lumps or ulcers and swollen lymph nodes.

An ECP service is indicated for the management of CTCL in patients who have experienced disease progression or unacceptable toxicity on other systemic treatments for CTCL. It is an apheresis-based immunomodulatory therapy performed via intravenous access, comprising three stages: leukapheresis, photoactivation and reinfusion. Blood is passed through multiple cycles of leukapheresis.

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This proposal was supported by the Medical Services Advisory Committee (MSAC) in April 2020 (MSAC application 1420.1).

### 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 advances the rights to health and the right to social security by listing a new service for the treatment of cutaneous T-cell lymphoma (CTCL) with extracorporeal photopheresis (ECP). This change will meet a previously unmet clinical need and will ensure there is equitable patient access to this service.

#### **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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