

EXPLANATORY STATEMENT

Health Insurance Act 1973

Health Insurance (Section 3C General Medical Services – Extracorporeal Photopheresis for Chronic Graft Versus Host Disease) Amendment Determination 2023

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 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 2021*.

This instrument relies on subsection 33(3) of the *Acts Interpretation Act 1901* (AIA). Subsection 33(3) of the AIA 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 *Health Insurance (Section 3C General Medical Services – Extracorporeal Photopheresis for Chronic Graft Versus Host Disease) Amendment Determination 2023* (the Determination) amends the *Health Insurance (Section 3C General Medical Services – Extracorporeal Photopheresis for Chronic Graft Versus Host Disease) Determination 2022* (the Principal Determination). The Determination amends the claiming frequency limitations of items 13761 and 13762, in line with the original policy authority.

Items 13761 and 13762 were introduced on 1 March 2022 for the treatment of chronic graft-versus-host disease (cGVHD) by extracorporeal photopheresis (ECP), in alignment with the pharmaceutical methoxalen being listed on the Pharmaceutical Benefits Scheme (PBS). Item 13761 provides a service for the initial treatment of ECP for cGVHD, where item 13762 provides a service for the ongoing treatment of ECP for cGVHD.

ECP is delivered using a single use device, in conjunction with the drug methoxalen, at each treatment session over an initial cycle of 25 treatment sessions.

The Medical Services Advisory Committee (MSAC) supported the listing of items 13761 and 13762 at its July 2021 meeting under MSAC application 1651. However, due to a misunderstanding of the policy intention, the frequency restriction placed on items 13761 and 13762 stated the items were applicable only once per treatment cycle. The amendments made by the Determination were discussed at MSAC's meeting of 19 August 2022.

The Determination inserts a definition for treatment session to clarify that a treatment session means a single session in a series of sessions that make up a treatment cycle. The

Determination also amends the current restriction to specify that items 13761 and 13762 are applicable once per treatment session.

Consultation

The MSAC reviews new or existing medical services or technology and makes recommendations as to the circumstances under which public funding should be supported. This includes the listing of new items, or amendments to existing items under Medicare.

As part of the MSAC process, consultation was undertaken with the Royal Prince Alfred Hospital Sydney as a key stakeholder.

Details of the Determination are set out in the Attachment.

The Determination commences on 1 July 2023.

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

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

ATTACHMENT

Details of the Health Insurance (Section 3C General Medical Services – Extracorporeal Photopheresis for Chronic Graft Versus Host Disease) Amendment Determination 2023Section 1 – Name

Section 1 provides for the Determination to be referred to as the *Health Insurance (Section 3C General Medical Services – Extracorporeal Photopheresis for Chronic Graft Versus Host Disease) Amendment Determination 2023*.

Section 2 – Commencement

Section 2 provides that the Determination commences on 1 July 2023.

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 General Medical Services – Extracorporeal Photopheresis for Chronic Graft Versus Host Disease) Determination 2022***

Item [1] repeals and replaces subsection 4(1) of the Principal Determination as the definitions were listed out of alphabetical order. This change is considered minor and administrative in nature.

Item [2] repeals and replaces section 7 of the Principal Determination to amend the heading of the section and insert an application clause to define a treatment session. Under this change, the heading for section 7 will be amended to read “Application of treatment cycle and session”, and subsection 7(2) will define a treatment session as a single session in a series of sessions that make up a treatment cycle.

The amendment of section 7 will ensure future services under items 13761 and 13762 are provided as intended. This change is considered minor and administrative in nature.

Item [3] amends item 13761 to revise the item descriptor. This change corrects a typographical error in the spelling of methoxsalen and revises and amends subparagraph (b) to clarify that a service under item 13761 is available to patients who have not previously received extracorporeal photopheresis treatment.

Item [3] also amends the frequency limitation on item 13761 to clarify that a service under item 13761 is applicable once per treatment session. This change ensures the frequency limitation applied to item 13761 is consistent with the original policy authority of the service.

Item [4] corrects a typographical error in the spelling of methoxsalen and amends the frequency limitation on item 13762 to clarify that a service under item 13761 is applicable once per treatment session. This change ensures the frequency limitation applied to item 13762 is consistent with the original policy authority of the service.

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 for Chronic Graft Versus Host Disease) Amendment Determination 2023

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 (Section 3C General Medical Services – Extracorporeal Photopheresis for Chronic Graft Versus Host Disease) Amendment Determination 2023* (the Determination) amends the *Health Insurance (Section 3C General Medical Services – Extracorporeal Photopheresis for Chronic Graft Versus Host Disease) Determination 2022* (the Principal Determination). The Determination amends the claiming frequency limitations of items 13761 and 13762, in line with the original policy authority.

Items 13761 and 13762 were introduced on 1 March 2022 for the treatment of chronic graft-versus-host disease (cGVHD) by extracorporeal photopheresis (ECP), in alignment with the pharmaceutical methoxalen being listed on the Pharmaceutical Benefits Scheme (PBS). Item 13761 provides a service for the initial treatment of ECP for cGVHD, where item 13762 provides a service for the ongoing treatment of ECP for cGVHD.

ECP is delivered using a single use device, in conjunction with the drug methoxalen, at each treatment session over an initial cycle of 25 treatment sessions.

The Medical Services Advisory Committee (MSAC) supported the listing of items 13761 and 13762 at its July 2021 meeting under MSAC application 1651. However, due to a misunderstanding of the policy intention, the frequency restriction placed on items 13761 and 13762 stated the items were applicable only once per treatment cycle. The amendments made by the Determination were discussed at MSAC's meeting of 19 August 2022.

The Determination inserts a definition for treatment session to clarify that a treatment session means a single session in a series of sessions that make up a treatment cycle. The Determination also amends the current restriction to specify that items 13761 and 13762 are applicable once per treatment session.

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 will reflect contemporary clinical practice to provide access to the amended medical services more frequently in line with the original policy intent, and ensure that patients continue to have access to health and social security through relevant subsidised medical services on the Medicare Benefits Schedule.

Conclusion

This instrument is compatible with human rights as it advances the right to health, the right to social security and the rights of equality and non-discrimination by amending the frequency limitation on the relevant subsidised medical services to allow patients to access the service more frequently.

Daniel McCabe
First Assistant Secretary
Medicare Benefits and Digital Health Division
Health Resourcing Group
Department of Health and Aged Care