

EXPLANATORY STATEMENT

Health Insurance Act 1973

Health Insurance (Section 3C General Medical Services – Botox, Dysport or Xeomin Injection) Amendment 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 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.

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 purpose of the *Health Insurance (Section 3C General Medical Services – Botox, Dysport or Xeomin Injection) Amendment Determination 2020* (the Amendment Determination) is to amend the *Health Insurance (Section 3C General Medical Services – Botox, Dysport or Xeomin Injection) Determination 2020* (the Principal Determination) from 1 August 2020.

Item 18365 commenced on 1 April 2015 for provision of the injection of multiple brands of botulinum toxin (Botox, Dysport and Xeomin) for the treatment of moderate to severe spasticity of the upper limb following a stroke.

The Amendment Determination will expand the eligibility for the administration of botulinum toxin (Botox, Dysport and Xeomin) to allow access to patients who have moderate to severe spasticity of the upper limb following an acute event, including stroke.

This proposal was considered by the Pharmaceutical Benefits Advisory Committee (PBAC) at its March and November 2019 meetings and supported by the Medical Services Advisory Committee (MSAC) Executive in December 2019.

Consultation

Botulinum toxin items on the Medicare Benefits Schedule (MBS) are co-dependant services as they can only be provided in accordance with the associated Pharmaceutical Benefits Scheme (PBS) criteria for the medicine. Approving the medicine (Botox, Dysport and Xeomin) and the injection service to be provided to a patient following an acute event therefore requires support from both PBAC and MSAC.

PBAC reviews new or existing medicines, and the circumstances under which public funding should be supported through listing on the PBS.

As part of the PBAC process for the related medicines, consultation is undertaken with professional bodies, consumer groups, the public and clinical experts for proposals put forward for consideration by PBAC.

Details of the Amendment Determination are set out in the Attachment.

The Amendment Determination commences on 1 August 2020.

The Amendment 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 – Botox, Dysport or Xeomin Injection) Amendment Determination 2020Section 1 – Name

Section 1 provides for the Determination to be referred to as the *Health Insurance (Section 3C General Medical Services – Botox, Dysport or Xeomin Injection) Amendment Determination 2020*.

Section 2 – Commencement

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

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 – Botox, Dysport or Xeomin Injection) Determination 2020***

Item 1 amends item 18365 by omitting “stroke” and substituting with “acute event”. This change expands the eligibility from ‘stroke’ to ‘an acute event’ for the administration of botulinum toxin (Botox, Dysport and Xeomin) for the treatment of moderate to severe spasticity of the upper limb.

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 – Botox, Dysport or Xeomin Injection) Amendment 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 – Botox, Dysport or Xeomin Injection) Amendment Determination 2020* (the Amendment Determination) is to amend the *Health Insurance (Section 3C General Medical Services – Botox, Dysport or Xeomin Injection) Determination 2020* (the Principal Determination) from 1 August 2020.

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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 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 right to health and social security by expanding the eligibility criteria for the provision of medicine for treatment for patients with moderate to severe spasticity of the upper limb following an acute event.

Conclusion

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

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