

EXPLANATORY STATEMENT

Health Insurance Act 1973

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

Item 18361 commenced on 1 July 2011 for the injection of botulinum toxin (Botox) for the treatment of moderate to severe upper limb spasticity due to cerebral palsy. This service can only be provided to patients who are at least 2 years of age. For patients who are at least 18 years old, it is a requirement that they have commenced treatment for the spasticity with botulinum toxin supplied under the Pharmaceutical Benefits Scheme (PBS).

The Amendment Determination will expand item 18361 to include Clostridium Botulinum Type A Toxin-Haemagglutinin Complex (Dysport®) as an acceptable alternative treatment, and will remove the requirement for patients who are at least 18 years old to have commenced treatment for the spasticity with botulinum toxin supplied under the PBS, prior to them turning 18 years old.

This change will align the delivery service of botulinum toxin for moderate to severe upper limb spasticity due to cerebral palsy with the criteria for the PBS listed medicines, and will improve patient access to clinically proven medicines with appropriate restrictions.

This proposal was considered by the Pharmaceutical Benefits Advisory Committee (PBAC) at in July 2020 and supported by the Medical Services Advisory Committee (MSAC) in July 2020.

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 PBS criteria for the medicine. Approving the medicine (Botox and Dysport) and the injection service to be provided 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. Consultation on the changes to item 18361 was also undertaken with relevant medicine sponsors.

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

The Amendment Determination commences on 1 December 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

Details of the Health Insurance (Section 3C General Medical Services – Botox Injection) Amendment Determination 2020

Section 1 – Name

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

Section 2 – Commencement

Section 2 provides that the Determination commences on 1 December 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 Injection) Determination 2020

Item 1 repeals and replaces item 18361 to provide that the service can also include an injection of Clostridium Botulinum Type A Toxin-Haemagglutinin Complex (Dysport®) as an alternative treatment, and to remove the requirement for patients who are at least 18 years old to have commenced treatment for the spasticity with botulinum toxin supplied under the PBS, prior to them turning 18 years old.

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 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

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The Amendment Determination will expand item 18361 to include Clostridium Botulinum Type A Toxin-Haemagglutinin Complex (Dysport®) as an acceptable alternative treatment, and will remove the requirement for patients who are at least 18 years old to have commenced treatment for the spasticity with botulinum toxin supplied under the PBS, prior to them turning 18 years old.

This change will align the delivery service of botulinum toxin for moderate to severe upper limb spasticity due to cerebral palsy with the criteria for the PBS listed medicines, and will improve patient access to clinically proven medicines with appropriate restrictions.

This proposal was considered by the Pharmaceutical Benefits Advisory Committee (PBAC) at in July 2020 and supported by the Medical Services Advisory Committee (MSAC) in July 2020.

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 aligning the delivery service of botulinum toxin for moderate to severe upper limb spasticity due to cerebral palsy with the criteria for the PBS listed medicines, and by improving patient access to clinically proven medicines with appropriate restrictions.

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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