

## EXPLANATORY STATEMENT

Issued by the Authority of the Minister for Health

*Health Insurance Act 1973*

*Health Insurance (Section 3C General Medical Services – Botox, Dysport or Xeomin Injection) 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 2019*. This version will be remade on 1 May 2020 by the *Health Insurance (General Medical Services Table) Regulations (No. 1) 2020*.

### **Purpose**

The purpose of the *Health Insurance (Section 3C General Medical Services – Botox, Dysport or Xeomin Injection) Determination 2020* (the Determination) is to continue to provide the legal basis for Medicare Benefits Schedule item 18365 (for the injection of botox for the treatment of moderate to severe spasticity of the upper limb following a stroke). Item 18365 was removed from the *Health Insurance (General Medical Services Table) Regulations (No. 1) 2020* to allow for a possible expansion of this service.

Expansion of the listing of three medicines associated with this item was considered by the Pharmaceutical Benefits Advisory Committee at its March 2019 and November 2019 meetings. Subject to policy authority, changes to this item and one of the three currently listed medicines are anticipated in the coming months.

Listing item 18365 in this Determination is an administrative change, which will provide for the implementation of required changes to be made as soon as possible. The Determination does not change the service provided under item 18365, and eligible patients will continue to be able to access the service.

### **Consultation**

No consultation was undertaken on this Determination as it is administrative in nature. The Determination lists current item 18365 and no changes have occurred to the service.

Details of the Determination are set out in the [Attachment](#).

The Determination commences on 1 May 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*

## ATTACHMENT

***Details of the Health Insurance (Section 3C General Medical Services – Botox, Dysport or Xeomin Injection) 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, Dysport or Xeomin Injection) 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.

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 item 18365 to the Determination was specified in the relevant provision in the general medical services table.

Subsection 6(1) of the Determination provides that item 18365 will be treated as if it was specified in clause 5.8.1 of the general medical services table. Clause 5.8.1 provides that the service does not include the supply of the botulinum toxin.

Subsection 6(2) of the Determination provides that item 18365 will be treated as if it was specified in subclause 5.8.2(2) and 5.8.2(3) of the general medical services table. Subclause 5.8.2(2) provides that the service is applicable to the first four treatments, but not exceeding two for each limb, in any one day. Subclause 5.8.2(3) provides that the service can only be provided by a specialist or consultant physician in the practice of the specialist's or consultant physician's speciality.

Schedule 1 – Relevant services

The Schedule specifies the service and the associated fee for item 18365.

## 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)  
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) Determination 2020* (the Determination) is to continue to provide the legal basis for Medicare Benefits Schedule item 18365 (for the injection of botox for the treatment of moderate to severe spasticity of the upper limb following a stroke). Item 18365 was removed from the *Health Insurance (General Medical Services Table) Regulations (No. 1) 2020* to allow for a possible expansion of this service.

Expansion of the listing of three medicines associated with this item was considered by the Pharmaceutical Benefits Advisory Committee at its March 2019 and November 2019 meetings. Subject to policy authority, changes to this item and one of the three currently listed medicines are anticipated in the coming months.

Listing item 18365 in this Determination is an administrative change, which will provide for the implementation of required changes to be made as soon as possible. The Determination does not change the service provided under item 18365, and eligible patients will continue to be able to access the service.

### 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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