

EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (HIGHLY SPECIALISED DRUGS PROGRAM) SPECIAL ARRANGEMENT AMENDMENT (APRIL UPDATE) INSTRUMENT 2021

PB 28 of 2021

Authority

Subsection 100(1) of the *National Health Act 1953* (the Act) enables the Minister to make special arrangements for the supply of pharmaceutical benefits.

Subsection 100(2) of the Act provides that the Minister may vary or revoke a special arrangement made under subsection 100(1).

Subsection 100(3) of the Act provides that Part VII of the Act, and instruments made for the purposes of Part VII have effect subject to a special arrangement made under subsection 100(1).

Purpose

This is the *National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (April Update) Instrument 2021* (PB 28 of 2021) (this Instrument). The purpose of this Instrument, made under subsection 100(2) of the Act, is to amend the *National Health (Highly Specialised Drugs Program) Special Arrangement 2021* (PB 27 of 2021) (the Special Arrangement), to make changes to the Special Arrangement relating to the Highly Specialised Drugs program.

The amendments made by this Instrument reflect amendments to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012), which commence on the same day. The *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012) is made under sections 84AF, 84AK, 85, 85A, 88 and 101 of the Act.

Schedule 1 to this Instrument provides for the addition of the listed drug dupilumab, the addition of three forms of the listed drug adalimumab and the addition of thirteen brands of existing pharmaceutical items to the Special Arrangement. It also provides for the deletion of two brands of pharmaceutical items from the Special Arrangement and the alteration of circumstances in which a prescription may be written for the supply of the listed drugs adalimumab, apomorphine, benralizumab, mepolizumab and omalizumab under the Special Arrangement. These changes are summarised, by subject matter, in the Attachment.

Consultation

The amendments made by this Instrument accord with recommendations made by the Pharmaceutical Benefits Advisory Committee (PBAC).

An ongoing and formal process of consultation in relation to matters relevant to the Special Arrangement includes the involvement of interested parties through the membership of the PBAC.

PBAC is an independent expert body established by section 100A of the Act which makes recommendations to the Minister about which drugs and medicinal preparations should be available as pharmaceutical benefits. PBAC members are appointed following nomination by prescribed organisations and associations from consumers, health economists, practising community pharmacists, general practitioners, clinical pharmacologists and specialists, with at least one member selected from each of those interests or professions. Remaining members are persons whom the Minister is satisfied have qualifications and experience in a field relevant to the functions of PBAC, and that would enable them to contribute meaningfully to the deliberations of PBAC. In addition, an industry nominee has been appointed to the PBAC membership. When recommending the listing of a medicine on the Pharmaceutical Benefits Scheme (PBS), PBAC takes into account the medical conditions for which the medicine has been approved for use in Australia, its clinical effectiveness, safety and cost-effectiveness compared with other treatments.

Pharmaceutical companies were consulted throughout the process of changes to the listings on the PBS. This includes consultation through the PBAC process.

Further consultation for this Instrument was considered unnecessary due to the nature of the consultation that had already taken place in the decision to list the medication.

Details of this Instrument are set out in the Attachment.

This Instrument commences on 1 April 2021.

This Instrument is a legislative instrument for the purposes of the *Legislation Act 2003*.

PROVISION-BY-PROVISION DESCRIPTION OF NATIONAL HEALTH (HIGHLY SPECIALISED DRUGS PROGRAM) SPECIAL ARRANGEMENT AMENDMENT (APRIL UPDATE) INSTRUMENT 2021

Section 1 Name of Instrument

This section provides the name of this Instrument as the *National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (April Update) Instrument 2021* and may also be cited as PB 28 of 2021.

Section 2 Commencement

This section provides that this Instrument commences on 1 April 2021, immediately after the commencement of the *National Health (Highly Specialised Drugs Program) Special Arrangement 2021* (PB 27 of 2021).

Section 3 Amendment of *National Health (Highly Specialised Drugs Program) Special Arrangement 2021* (PB 27 of 2021)

This section provides that Schedule 1 amends the *National Health (Highly Specialised Drugs Program) Special Arrangement 2021* (PB 27 of 2021).

Schedule 1 Amendments

The amendments in Schedule 1 involve the addition of a drug, the addition of forms of a listed drug, the addition and deletion of brands, and the alteration of circumstances for prescribing various listed drugs available under the Special Arrangement. These changes are summarised below.

SUMMARY OF CHANGES TO THE NATIONAL HEALTH (HIGHLY SPECIALISED DRUGS PROGRAM) SPECIAL ARRANGEMENT 2021 MADE BY THIS INSTRUMENT

Listed Drugs Added

Listed Drug

Dupilumab

Forms Added

Listed Drug	Form
Adalimumab	Injection 20 mg in 0.2 mL pre-filled syringe
	Injection 40 mg in 0.4 mL pre-filled pen
	Injection 40 mg in 0.4 mL pre-filled syringe

Brands Added

Listed Drug	Form and Brand
Adalimumab	Injection 20 mg in 0.4 mL pre-filled syringe (<i>Amgevita</i>)
	Injection 40 mg in 0.8 mL pre-filled syringe (<i>Amgevita; Hadlima; Hyrimoz; Idacio</i>)
	Injection 40 mg in 0.8 mL pre-filled pen (<i>Amgevita; Hadlima; Hyrimoz; Idacio</i>)

Cinacalcet	Tablet 30 mg (as hydrochloride) (<i>Cinacalcet Mylan</i>)
	Tablet 60 mg (as hydrochloride) (<i>Cinacalcet Mylan</i>)
	Tablet 90 mg (as hydrochloride) (<i>Cinacalcet Mylan</i>)
Tenofovir	Tablet containing tenofovir disoproxil fumarate 300 mg (<i>Tenofovir Sandoz</i>)

Brands Deleted

<i>Listed Drug</i>	<i>Form and Brand</i>
Rituximab	Solution for I.V. infusion 100 mg in 10 mL (<i>Mabthera</i>)
	Solution for I.V. infusion 500 mg in 50 mL (<i>Mabthera</i>)

Alteration of Circumstances in Which a Prescription May be Written

Listed Drug

Adalimumab
 Apomorphine
 Benralizumab
 Mepolizumab
 Omalizumab

Documents incorporated by reference

<i>Listed Drug</i>	<i>Document incorporated</i>	<i>Document access</i>
Adalimumab Benralizumab Dupilumab Mepolizumab Omalizumab	Therapeutic Goods Administration (TGA)-approved Product Information. The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the <i>Legislation Act 2003</i> . This document provides health professionals with a summary of the scientific information relevant to the safe and effective use of a prescription medicine.	TGA-approved Product Information is available for download for free from the TGA website: https://www.tga.gov.au/product-information-0
Benralizumab Dupilumab Mepolizumab Omalizumab	Asthma Control Questionnaire (ACQ-5) and/or Asthma Control Questionnaire interviewer administered version (ACQ-IA). The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the <i>Legislation Act 2003</i> . The ACQ-5 and the ACQ-IA are widely used tools for measuring how well a patient's asthma symptoms are being controlled.	Prescribers can contact the suppliers of these asthma medications directly to obtain free copies of the ACQ calculation sheets. Contact details for the suppliers can be found online at www.pbs.gov.au
Infliximab Vedolizumab	Crohn's Disease Activity Index (CDAI). The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the <i>Legislation Act 2003</i> . The Crohn's Disease Activity Index (CDAI) is a research tool used to quantify the symptoms of patients with Crohn's disease.	The CDAI is available for download for free from the Gastroenterology journal website www.gastrojournal.org/article/S0016-5085(76)80163-1/abstract

Vedolizumab

Mayo clinic score and the partial Mayo clinic score.

The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the Legislation Act 2003.

The Mayo clinic score and the partial Mayo clinic score (an abbreviated form of the Mayo clinic score) are standard medical diagnostic tools used to measure disease activity in Ulcerative Colitis through the evaluation of symptoms.

The Mayo clinic score and the partial Mayo clinic score are available for download for free from the IG-IBD Scores - Calculators in gastroenterology website www.igibdscores.it/en/

Statement of Compatibility with Human Rights

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

National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (April Update) Instrument 2021

(PB 28 of 2021)

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 Instrument

The purpose of this Instrument, made under subsection 100(2) of the *National Health Act 1953* (the Act), is to amend the *National Health (Highly Specialised Drugs Program) Special Arrangement 2021* (PB 27 of 2021) (the Special Arrangement), to make changes to the Special Arrangement relating to the Highly Specialised Drugs program.

The pharmaceutical benefits supplied under the Special Arrangement are for the treatment of chronic conditions which, because of their clinical use or other special features, may only be supplied to patients receiving specialised treatment.

The amendments in Schedule 1 involve the addition of a drug, the addition of forms of a listed drug, the addition and deletion of brands, and the alteration of circumstances for prescribing various listed drugs available under the Special Arrangement.

Human Rights Implications

This Instrument engages Article 2 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) by assisting with the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The Pharmaceutical Benefits Scheme (PBS) is a benefit scheme which assists with advancement of this human right by providing for subsidised access by patients to medicines. The recommendatory role of the Pharmaceutical Benefits Advisory Committee (PBAC) ensures that decisions about subsidised access to medicines on the PBS are evidence-based.

Conclusion

This Instrument is compatible with human rights because it advances the protection of human rights.

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