EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (HIGHLY SPECIALISED DRUGS PROGRAM) SPECIAL ARRANGEMENT AMENDMENT (JULY UPDATE) INSTRUMENT 2024

PB 71 of 2024

Purpose

This is the *National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (July Update) Instrument 2024* (PB 71 of 2024) (this 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 (HSD) Program.

The amendments made by this Instrument reflect amendments to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (PB 26 of 2024), which commence on the same day. The *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (PB 26 of 2024) is made under sections 84AF, 84AK, 85, 85A, 88 and 101 of the Act.

Schedule 1 to this Instrument provides for the interim addition of the listed drug daunorubicin with cytarabine to the HSD Program. Daunorubicin with cytarabine is the second combination medicine (as it contains more than one active ingredient in a single pre-mixed vial) to be listed on the HSD Special Arrangement.

It also provides for the addition of the listed drug anifrolumab, the addition of forms of the listed drug octreotide, the addition of a brand of the listed drugs octreotide and sevelamer, the alteration of number of repeats for the listed drugs buprenorphine, buprenorphine with naloxone, and methadone, and for the alteration of circumstances in which a prescription may be written for the listed drugs avatrombopag, benralizumab, buprenorphine, buprenorphine with naloxone, ciclosporin, dupilumab, mepolizumab, methadone, omalizumab, and selinexor under the Special Arrangement.

These changes are summarised, by subject matter, in the Attachment.

Authority

Subsection 100(1) of 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).

Background for daunorubicin with cytarabine listing

Daunorubicin with cytarabine received a positive recommendation from the Pharmaceutical Benefits Advisory Committee (PBAC) in November 2023 for the treatment of patients with therapy-related acute myeloid leukaemia (t-AML) or acute myeloid leukaemia with myelodysplasia-related changes (AML-MRC), on the basis that it should be available under the Section 100 Efficient Funding of Chemotherapy (EFC) Program.

The Department of Health and Aged Care in consultation with Services Australia determined that extensive system and administrative changes would be required for both the Department and Services Australia to facilitate the inclusion of a combination medicine on the EFC Program. Delaying this listing until current systems are able to recognise a combination medicine would, however, disadvantage patients seeking treatment with these medicines.

At the April 2024 PBAC out of session meeting, daunorubicin with cytarabine received a positive recommendation for listing on the HSD Program as an interim listing. Daunorubicin with cytarabine is the second combination medicine to be recommended for an HSD Program listing.

While daunorubicin with cytarabine is listed on the HSD Program, as the system cannot administer an HSD medicine with the same parameters as an EFC medicine, patients will not be able to access this medicine under the same conditions as if it were listed on the EFC Program. The HSD Program listing of daunorubicin with cytarabine will attract a patient co-payment for each repeat prescription, whereas under the EFC Program, patients do not pay for repeat supplies of the medicine. The Department understands the additional financial burden this may place on patients, however, the availability of daunorubicin with cytarabine on the Pharmaceutical Benefits Scheme (PBS) provides for subsidised access to the medicine that would not be available if a listing on the HSD Program was not considered.

Consultation

The amendments made by this Instrument accord with recommendations made by the Pharmaceutical Benefits Advisory Committee (PBAC), including in relation to the inclusion of daunorubicin with cytarabine on the HSD Special Arrangement.

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.

The Department consulted with the sponsor of daunorubicin with cytarabine regarding the challenges posed with listing a combination medicine on the EFC Program. The sponsor was made aware that the required system and administrative changes would delay the listing of daunorubicin with cytarabine on the EFC Program.

The sponsor was supportive of having daunorubicin with cytarabine listed on the HSD Program until the EFC Program could be modified to enable the listing. Although patients will not be able to access this medicine under the same conditions as if it were listed on the EFC Program, listing the medicine on the HSD Program is a positive interim solution. This solution enables patients to access daunorubicin with cytarabine at a PBS subsidised price rather than delaying access and charging patients private fees for this medicine.

The Department is continuing to consult and work with Services Australia regarding system and administrative changes required to facilitate the future listing of daunorubicin with cytarabine on the EFC Program.

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 has already taken place in the decision to list the medications outlined under ‘Purpose’.

Details of this Instrument are set out in the Attachment.

This Instrument commences on 1 July 2024.

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

ATTACHMENT

DETAILS OF THE *NATIONAL HEALTH (HIGHLY SPECIALISED DRUGS PROGRAM) SPECIAL ARRANGEMENT AMENDMENT (JULY UPDATE) INSTRUMENT 2024*

Section 1 Name of Instrument

This section provides that the name of the Instrument is the *National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (July Update) Instrument 2024* and may also be cited as PB 71 of 2024.

Section 2 Commencement

This section provides that this Instrument commences on 1 July 2024.

Section 3 Authority

This section states that this instrument is made under subsection 100(2) of the *National Health Act 1953*.

Section 4 Schedules

This section provides that each instrument that is specified in a Schedule to the Instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the Instrument has effect according to its terms.

Schedule 1 Amendments

The amendments in Schedule 1 involve the addition of listed drugs, the addition of forms of listed drugs, the addition of brands of listed drugs, the alteration of number of repeats for listed drugs, and the alteration of circumstances in which a prescription may be written for various listed drugs available under the Special Arrangement. These changes are summarised below.

SUMMARY OF CHANGES TO THE *HIGHLY SPECIALISED DRUGS PROGRAM* MADE BY THIS INSTRUMENT

Drugs Added

Listed Drug

Anifrolumab

Daunorubicin with cytarabine

Forms Added

Listed Drug	***Form***
Octreotide	Injection 50 micrograms (as acetate) in 1 mL (S19A)
	Injection 100 micrograms (as acetate) in 1 mL (S19A)

Brands Added

Listed Drug	***Form and Brand***
Octreotide	Injection 500 micrograms (as acetate) in 1 mL *(Octreotide Acetate Omega (Canada))*

Sevelamer	Tablet containing sevelamer carbonate 800 mg *(ARX-SEVELAMER)*	

Alteration of Number of Repeats

Listed Drug	*Form*	*Brand*	*Maximum Quantity*	*Number of Repeats*	
Buprenorphine	Injection (modified release) 8 mg in 0.16 mL pre-filled syringe	*Buvidal Weekly*	4	***From:*** 2	***To:*** 5
	Injection (modified release) 16 mg in 0.32 mL pre-filled syringe	*Buvidal Weekly*	4	***From:*** 2	***To:*** 5
	Injection (modified release) 24 mg in 0.48 mL pre-filled syringe	*Buvidal Weekly*	4	***From:*** 2	***To:*** 5
	Injection (modified release) 32 mg in 0.64 mL pre-filled syringe	*Buvidal Weekly*	4	***From:*** 2	***To:*** 5
	Injection (modified release) 64 mg in 0.18 mL pre-filled syringe	*Buvidal Monthly*	1	***From:*** 2	***To:*** 5
	Injection (modified release) 96 mg in 0.27 mL pre-filled syringe	*Buvidal Monthly*	1	***From:*** 2	***To:*** 5
	Injection (modified release) 100 mg in 0.5 mL pre-filled syringe	*Sublocade*	1	***From:*** 2	***To:*** 5
	Injection (modified release) 128 mg in 0.36 mL pre-filled syringe	*Buvidal Monthly*	1	***From:*** 2	***To:*** 5
	Injection (modified release) 160 mg in 0.45 mL pre-filled syringe	*Buvidal Monthly*	1	***From:*** 2	***To:*** 5
	Injection (modified release) 300 mg in 1.5 mL pre-filled syringe	*Sublocade*	1	***From:*** 2	***To:*** 5
	Tablet (sublingual) 400 micrograms (as hydrochloride)	*Subutex*	28	***From:*** 2	***To:*** 5
	Tablet (sublingual) 2 mg (as hydrochloride)	*Subutex*	84	***From:*** 2	***To:*** 5
	Tablet (sublingual) 8 mg (as hydrochloride)	*Subutex*	112	***From:*** 2	***To:*** 5
Buprenorphine with naloxone	Film (soluble) 2 mg (as hydrochloride)-0.5 mg (as hydrochloride)	*Suboxone Film 2/0.5*	84	***From:*** 2	***To:*** 5
	Film (soluble) 8 mg (as hydrochloride)-2 mg (as hydrochloride)	*Suboxone Film 8/2*	112	***From:*** 2	***To:*** 5
Methadone	Oral liquid containing methadone hydrochloride 25 mg per 5 mL in 1 L bottle, 1 mL	*Aspen Methadone Syrup*	840	***From:*** 2	***To:*** 5

	Biodone Forte	840	***From:*** 2	***To:*** 5
Oral liquid containing methadone hydrochloride 25 mg per 5 mL in 200 mL bottle, 1 mL	*Aspen Methadone Syrup*	840	***From:*** 2	***To:*** 5
	Biodone Forte	840	***From:*** 2	***To:*** 5

Alteration of Circumstances in Which a Prescription May be Written

Listed Drug

Avatrombopag	Dupilumab
Benralizumab	Mepolizumab
Buprenorphine	Methadone
Buprenorphine with naloxone	Omalizumab
Ciclosporin	Selinexor

Documents Incorporated by Reference

Listed Drug	***Document incorporated***	***Document access***
Anifrolumab	**American College of Rheumatology (ACR)/European League Against Rheumatism (EULAR) Systemic Lupus Erythematosus (SLE) Classification Criteria 2019**. 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 ACR/EULAR SLE Classification Criteria 2019 provide a comprehensive framework for diagnosing the autoimmune disease systemic lupus erythematosus.	The ACR/EULAR SLE Classification Criteria 2019 is available for download for free from the National Library of Medicine, National Center of Biotechnology Information website: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6827566/ Aringer M et al. 2019 European League Against Rheumatism/American College of Rheumatology Classification Criteria for Systemic Lupus Erythematosus. Arthritis Rheumatol. 2019 Sep;71(9):1400-1412. doi: 10.1002/art.40930.
Anifrolumab Benralizumab Daunorubicin with cytarabine Dupilumab Mepolizumab Omalizumab	**Approved Product Information/Australian Product Information/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 *Legislation Act 2003.* 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 *Legislation Act 2003*. 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
Anifrolumab	**Physician global assessment (PGA)** (for systemic lupus erythematosus (SLE)). 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 PGA is a scale for clinician rating of overall disease activity in patients with SLE, taking into account the severity of active manifestations and clinical laboratory results, but excluding organ damage, serology, and subjective findings unrelated to disease activity.	The PGA is available for download for free from the Lancet Rhuematology website: https://www.thelancet.com/journals/lanrhe/article/PIIS2665-9913(22)00107-2/abstract It can also be accessed by contacting AstraZeneca Medical Information by phone on 1800 805 342 Piga, M. et al. Physician Global Assessment International Standardisation COnsensus in Systemic Lupus Erythematosus: the PISCOS study. Lancet Rheumatology 4, e441–e449 (2022)
Ciclosporin	**Psoriasis Area Severity Index (PASI).** 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 PASI is a widely used tool that enables measurement of the severity and extent of baseline and response of therapy in psoriasis.	The PASI calculation form is available for download for free from the Services Australia website: https://www.servicesaustralia.gov.au/ and forms part of the SA authority application process.
Anifrolumab	**Systemic lupus erythematosus (SLE) Disease Activity Index 2000 (SLEDAI-2K)**. 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 SLEDAI-2K is a global index for the assessment of lupus disease activity across clinical and laboratory variables of nine organ systems.	SLEDAI-2K is available for download for free from The Journal of Rhematology website: https://www.jrheum.org/content/29/2/288.long It can also be accessed by contacting AstraZeneca Medical Information by phone on 1800 805 342 Gladman 2002 J. Rheumatol. 29 (2) 288-291
Daunorubicin with cytarabine	**World Health Organization (WHO)/Eastern Cooperative Oncology Group (ECOG) Performance Status/Performance Status Score.**	The WHO/ECOG Performance Status is available for download for free from the ECOG-ACRIN Cancer Research Group website: https://ecog-acrin.org/resources/ecog-performance-status

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 WHO/ECOG performance status is a standard medical diagnostic tool used to measure how cancer impacts a patient's daily living abilities, by evaluating a patient's level of functioning in terms of their ability to care for themself, daily activity, and physical ability (walking, working, etc.).

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 (July Update) Instrument 2024

(PB 71 of 2024)

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.

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 social security and 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 UN Committee on Economic Social and Cultural Rights 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 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.

Analysis

This Instrument advances the right to health and the right to social security by ensuring that the amendments to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (the Listing Instrument), that affect the pharmaceutical benefits that may be supplied under the Special Arrangement, are made concurrently. This Instrument provides for the addition of the listed drugs anifrolumab and daunorubicin with cytarabine, the addition of forms of the listed drug octreotide, and the addition of a brand of the listed drugs octreotide and sevelamer.

The interim inclusion of the combination medicine, daunorubicin with cytarabine, on the HSD Program is compatible with and advances the right to health by ensuring that eligible patients will be in a position to obtain early PBS subsidised access to this drug, without which daunorubicin with cytarabine would only be available through private funding at a significantly greater cost to patients.

The Listing Instrument determines the pharmaceutical benefits that are on the Pharmaceutical Benefits Scheme (PBS) through declarations of drugs and medicinal preparations, and determinations of forms, manners of administration and brands. The PBS is a benefit scheme which assists with advancement of these human rights 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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