EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (EFFICIENT FUNDING OF CHEMOTHERAPY) SPECIAL ARRANGEMENT AMENDMENT (DECEMBER UPDATE) INSTRUMENT 2024

PB 128 of 2024

Purpose

This is the *National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment (December Update) Instrument 2024* (PB 128 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 (Efficient Funding of Chemotherapy) Special Arrangement 2024* (PB 31 of 2024) (the Special Arrangement) to make changes to the Special Arrangement relating to the Efficient Funding of Chemotherapy (EFC) Program, including changes relating to the transition of Opdualag® (nivolumab with relatlimab) and Vyxeos® (daunorubicin with cytarabine) from the Special Arrangement relating to the Highly Specialised Drugs (HSD) Program, consistent with the Pharmaceutical Benefits Advisory Committee (PBAC) recommendations.

The Special Arrangement achieves greater efficiency in payment for the supply of injected or infused chemotherapy medicines ('chemotherapy pharmaceutical benefits') to eligible patients being treated for cancer, to reflect the 2010 Budget measure titled 'Revised arrangements for the efficient funding of chemotherapy drugs'. The Special Arrangement also relates to the supply of medicines associated with the side-effects of cancer and cancer treatment ('related pharmaceutical benefits') at certain public hospitals.

This Instrument makes amendments to the Special Arrangement to reflect changes made to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (PB 26 of 2024) which commences 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.

The amendments made by this Instrument provide for the addition of the listed drugs daunorubicin with cytarabine and nivolumab with relatlimab, which are both transitioning from the Special Arrangement for the HSD Program as detailed below under "background for combination chemotherapy listings". It also provides for the deletion of a brand of the listed drug bortezomib, and the alteration of circumstances in which a prescription may be written for the listed drug elotuzumab 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 combination chemotherapy listings

Two medicines, Opdualag (nivolumab with relatlimab) and Vyxeos (daunorubicin with cytarabine), were initially recommended by the PBAC for listing on the Efficient Funding of Chemotherapy (EFC) Program. These medicines are referred to as 'combination items', which the *National Health Act 1953* (the Act) defines as 'a pharmaceutical item that has a drug that contains at least 2 other drugs or medicinal preparations, at least one of which is a listed drug'.

In March 2023, Opdualag was recommended by the PBAC to be listed on the EFC Program for the treatment of patients with unresectable Stage III or Stage IV malignant melanoma. In November 2023, Vyxeos was recommended by the PBAC for the treatment of patients with therapy-related acute myeloid leukaemia (t-AML) or acute myeloid leukaemia with myelodysplasia-related changes (AML-MRC).

Opdualag and Vyxeos were the first two 'combination items' that have been recommended by the PBAC for listing on the EFC Program. However, these medicines could not be listed on the EFC Program due to extensive system and administrative limitations for both the Department of Health and Aged Care (department) and Services Australia. Opdualag and Vyxeos were temporarily listed on the Highly Specialised Drugs (HSD) Program to facilitate subsidised patient access while the department sought to support the listing of combination items on the EFC Program. On 1 February 2024, Opdualag was listed on the HSD Program and on 1 July 2024, Vyxeos was listed on the HSD Program.

The department has reached a solution with the software system and is now able to transition these medicines to the EFC Program. The current system will list these medicines in the EFC Program by using the maximum amount for one ingredient against Pharmaceutical Benefits Scheme (PBS) claiming, with the full combination medicine description in the administrative notes.

Opdualag and Vyxeos will remain listed on the HSD Program for a period of 12 months under the special supply arrangements. This means that patients who had a PBS prescription written for either Opdualag or Vyxeos under the HSD Program, may continue to have unfilled prescriptions supplied under the previous arrangements.

There are different remuneration and access arrangements between the EFC and HSD Programs. It is not possible for the system to administer an HSD Program medicine with the same program policy of an EFC Program medicine. The HSD Program attracts a PBS patient co-payment for each repeat prescription, whereas under the EFC Program, patients do not pay for repeat supplies of the medicine. Transitioning Opdualag and Vyxeos to the Special Arrangement will ensure that patients will only pay the applicable PBS co-payment for their original prescription and will not pay the PBS co-payment for their repeat supplies.

Amendments are also being made to the *National Health (Highly Specialised Drugs Program) Special Arrangement 2021* (PB 27 of 2021) (via the *National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (December Update) Instrument 2024* (PB 127 of 2024)) to reflect the transitioning of Opdualag and Vyxeos from the HSD Program to the EFC Program. The *National Health (Highly Specialised Drugs Program) Special Arrangement Amendment (December Update) Instrument 2024* (PB 127 of 2024) commences on the same day as this Instrument.

The changes to this Special Arrangement are summarised, by subject matter, in the Attachment.

Consultations

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. The amendments made by this Instrument, including those amendments which relate to the transition of Opdualag and Vyxeos from the HSD Program, accords with recommendations by the PBAC.

The 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. Part VII of the Act only applies to drugs or medicinal preparations recommended by the PBAC. When recommending the listing of a medicine on the PBS, the PBAC takes into account the medical conditions for which the medicine has been approved for use in Australia and its clinical effectiveness, safety and cost-effectiveness compared with other treatments.

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 these interests or professions. Remaining members are persons whom the Minister is satisfied have qualifications and experience in a field relevant to the functions of the PBAC, and that would enable them to contribute meaningfully to the deliberations of the PBAC.

The department consulted with the sponsors of both Opdualag and Vyxeos regarding the challenges posed with listing combination medicines on the EFC Program. The sponsors were made aware that the required system and administrative changes would delay the listing of Opdualag and Vyxeos on the EFC Program. The sponsors were supportive of having Opdualag and Vyxeos listed on the HSD Program until the EFC Program could accommodate the listing.

Pharmaceutical companies are consulted throughout the process for additions and changes to listings on the Pharmaceutical Benefits Scheme (PBS), including consultation through the PBAC process and agreement to final listing details.

Services Australia was also consulted throughout this process to ensure that systems would be able to accommodate the listings of Opdualag and Vyxeos on the EFC Program.

It was considered that further consultation for this Instrument was unnecessary due to the nature of the consultation that has already taken place.

General

A provision-by-provision description of this instrument is contained in the Attachment.

This Instrument commences on 1 December 2024.

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

ATTACHMENT

PROVISION-BY-PROVISION DESCRIPTION OF *NATIONAL HEALTH (EFFICIENT FUNDING OF CHEMOTHERAPY) SPECIAL ARRANGEMENT AMENDMENT (DECEMBER UPDATE) INSTRUMENT 2024*

Section 1 Name of Instrument

This section provides that the name of the Instrument is the *National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment (December Update) Instrument 2024* and may also be cited as PB 128 of 2024.

Section 2 Commencement

This section provides that this Instrument commences on 1 December 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

Section 4 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

National Health (Efficient Funding of Chemotherapy) Special Arrangement 2024

Item 1 – Section 5

Item 1 inserts a new definition for 'active ingredient', being, in relation to a chemotherapy drug, a drug that is mentioned in the name of the chemotherapy drug. This is because the two new chemotherapy drugs are 'combination medicines'. Opdualag® (nivolumab with relatlimab) and Vyxeos® (daunorubicin with cytarabine) both contain two active ingredients in a vial, and it is important that both of these 'active ingredients' are taken into consideration when determining 'maximum quantities' and dosing regimens. This also provides a robust definition should future chemotherapy medicines be recommended by the Pharmaceutical Benefits Advisory Committee where there is more than one 'active ingredient' in a vial.

Item 2 – Subsection 14(2)

Item 2 inserts '(the maximum amount column)' in subsection 14(2) for clarity.

Item 3 – Subsection 14(3)

Item 3 omits 'column of the table in Part 2 of Schedule 1 headed "Maximum Amount" in relation to' and substitutes it with 'maximum amount column in relation to', ensuring subsection 14(3) is more reader friendly.

Item 4 – At the end of section 14

Item 4 inserts a new subsection and table in section 14 to explain how maximum amounts are dealt with when chemotherapy medicines have multiple active ingredients. Current systems do not allow for more than one maximum amount to be included as an entry. This new provision clearly sets out, in table format, which of the active ingredients is to be used for the purpose of prescribing combination chemotherapy medicines. This will ensure that any future listings of chemotherapy medicines with more than one active ingredient can be accommodated.

Item 5 – After section 14

Item 5 inserts a new section 14A, after section 14, to explain to prescribers how to correctly prescribe these two chemotherapy medicines as there are two active ingredients in each vial. It is important for prescribers to prescribe these medicines based on the proportions of each active ingredient contained in the vial.

Item 6 – After subsection 21(1)

Item 6 inserts a new subsection 21(1A), which requires that prescribers, if seeking to vary a patient's dose that is between 90% and 110% of the dose that was originally prescribed, must take into consideration the proportion of the active ingredients contained within a vial.

Item 7 – Subsections 21(2) and (3)

Item 7 omits 'subsection (1)' from subsections 21(2) and (3), and substitutes it with 'subsection (1) and (1A)' to allow for the inclusion of the new subsection at Item 6 above.

Items 8 to 17 involve the addition of listed drugs, the deletion of a brand of a listed drug and the alteration of circumstances in which a prescription may be written for a drug listed under the Special Arrangement. These changes are summarised below.

SUMMARY OF CHANGES TO THE *EFFICIENT FUNDING OF CHEMOTHERAPY PROGRAM* MADE BY THIS INSTRUMENT

Drugs Added

Listed Drug

Daunorubicin with cytarabine

Nivolumab with relatlimab

Brand Deleted

Listed Drug	***Form***
Bortezomib	Powder for injection 3.5 mg *(BORTEZOMIB TEVA)*

Alteration of Circumstances in Which a Prescription May be Written

Listed Drug

Elotuzumab

Documents Incorporated by Reference

Listed Drug	***Document incorporated***	***Document access***
Daunorubicin with cytarabine Nivolumab with relatlimab	**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

Daunorubicin with cytarabine Nivolumab with relatlimab	**World Health Organization (WHO)/Eastern Cooperative Oncology Group (ECOG) Performance Status/Performance Status 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 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.).	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

Statement of Compatibility with Human Rights

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

National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment (December Update) Instrument 2024

(PB 128 of 2024)

This Legislative 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 Legislative Instrument

The purpose of this Legislative Instrument, made under subsection 100(2) of the *National Health Act 1953* (the Act), is to amend the *National Health (Efficient Funding of Chemotherapy) Special Arrangement 2024* (PB 31 of 2024) (the Special Arrangement) to make changes relating to the Efficient Funding of Chemotherapy Program, including changes relating to the transition of two new chemotherapy medicines from the Highly Specialised Drug (HSD) Program consistent with a recommendation of the Pharmaceutical Benefits Advisory Committee (PBAC).

The Special Arrangement achieves greater efficiency in payment for the supply of injected or infused chemotherapy medicines ('chemotherapy pharmaceutical benefits') to eligible patients being treated for cancer, to reflect the 2010 Budget measure titled 'Revised arrangements for the efficient funding of chemotherapy drugs'. The Special Arrangement also relates to the supply of medicines associated with the side-effects of cancer and cancer treatment ('related pharmaceutical benefits') at certain public hospitals.

This Instrument provides for amendments to the Special Arrangement to ensure that the Special Arrangement accurately reflects changes to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2024* (the Listing Instrument), made under sections 84AF, 84AK, 85, 85A, 88 and 101 of the Act, which commences on the same day.

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 two new chemotherapy combination medicines, Opdualag and Vyxeos, for the Special Arrangement. The inclusion of the combination medicines Opdualag and Vyxeos on the EFC Program from 1 December 2024 is compatible with and advances the right to health by ensuring that eligible patients will continue to be in a position to obtain Pharmaceutical Benefits Scheme (PBS) subsidised access to these drugs, without which would they only be available through private funding at a significantly greater cost to patients.

This Instrument also provides for the deletion of a brand of the listed drug bortezomib.

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.

Where there are many brands of a listed drug and form, then the delisting of one brand will not adversely affect members of the public as they will be able to obtain any of the other equivalent brands. The delisting of a brand in this Instrument will not affect access to the drugs, as affected patients will be able to access equivalent brands, at the same cost. Consequently, the brand delistings in this instrument do not result in an unmet clinical need. Note that delisting of maximum quantities, number of repeats, and pack sizes are equivalent to brand delistings

Conclusion

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

Eden Simon
Assistant Secretary (Acting)
Pricing and PBS Policy Branch
Technology Assessment and Access Division
Department of Health and Aged Care