PB 45 of 2025

National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment (May Update) Instrument 2025

National Health Act 1953

I, REBECCA RICHARDSON, Assistant Secretary, Pricing and PBS Policy Branch, Technology Assessment and Access Division, Department of Health and Aged Care, delegate of the Minister for Health and Aged Care, make this Instrument under subsection 100(2) of the *National Health Act 1953*.

Dated 28 April 2025

REBECCA RICHARDSON
Assistant Secretary
Pricing and PBS Policy Branch
Technology Assessment and Access Division

Contents

1 Name

(1) This instrument is the *National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment (May Update) Instrument 2025.*

(2) This instrument may also be cited as PB 45 of 2025.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information

Column 1	Column 2	Column 3
Provisions	**Commencement**	**Date/Details**
1. *The whole of this instrument*	*1 May 2025*	*1 May 2025*

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

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

4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

Schedule 1—Amendments

National Health (Efficient Funding of Chemotherapy) Special Arrangement 2024 (PB 31 of 2024)

[1] Schedule 1, Part 1

insert as first entry:

Amivantamab	Solution concentrate for I.V. infusion 350 mg in 7 mL	Injection	Rybrevant	C16402 C16472

[2] Schedule 1, Part 1, entry for Dostarlimab

omit from the column headed "Circumstances": **C15196**

[3] Schedule 1, Part 2

insert as first entry:

Amivantamab	P16472	2100 mg	5
	P16402	2100 mg	7

[4] Schedule 1, Part 2, entry for Dostarlimab *[Maximum Amount: 1000 mg; Number of Repeats: 3]*

omit from the column headed "Purposes": **P15196**

[5] Schedule 2, after entry for Daratumumab *[Maximum Quantity: 1; Number of Repeats: 15]*

insert:

Epcoritamab	Solution concentrate for subcutaneous injection 4 mg in 0.8 mL	Injection	Epkinly	C16405	1	1
	Solution for subcutaneous injection 48 mg in 0.8 mL	Injection	Epkinly	C16465 C16466	1	9

[6] Schedule 3, Part 1, omit entry for Circumstances Code "C15196"

[7] Schedule 3, Part 1, after entry for Circumstances Code "C16375"

insert:

C16402	P16402	Amivantamab	Stage IIIB/ IIIC (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)	Compliance with Authority

		Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition.	Required procedures
C16405	Epcoritamab	Relapsed or refractory diffuse large B-cell lymphoma (DLBCL) Induction treatment The condition must have relapsed, or be refractory to, at least two prior systemic therapies; AND Patient must have a WHO performance status of no higher than 2; AND Patient must have previously received treatment with chimeric antigen receptor-T (CAR-T) cell therapy for this condition; OR Patient must be currently unable to receive treatment with CAR-T cell therapy for this condition; AND Patient must not be eligible for stem cell transplantation; AND The treatment must be discontinued in patients who experience disease progression whilst on treatment. Prior systemic therapy may include autologous stem cell transplant. Definition of patients unable to receive treatment with CAR-T cell therapy for this condition include geographical, psychosocial, clinical ineligibility or urgency.	Compliance with Authority Required procedures
C16465	Epcoritamab	Relapsed or refractory diffuse large B-cell lymphoma (DLBCL) Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements Patient must have received non-PBS-subsidised treatment with this drug for this PBS condition prior to 1 May 2025; AND The condition must have relapsed, or be refractory to, at least two prior systemic therapies, prior to commencing treatment with this drug; AND Patient must have had a WHO performance status of no higher than 2 prior to commencing treatment with this drug for this condition; AND Patient must have previously received treatment with chimeric antigen receptor-T (CAR-T) cell therapy for this condition; OR Patient must have been unable to receive treatment with CAR-T cell therapy for this condition; AND Patient must not be eligible for stem cell transplantation; AND The treatment must be discontinued in patients who experience disease progression whilst on treatment. Patient must be undergoing treatment with this drug administered weekly in cycles 1 to 3 - prescribe up to 9 repeats; OR Patient must be undergoing treatment with this drug administered fortnightly in cycles 4 to 9 -	Compliance with Authority Required procedures

			prescribe up to 5 repeats; OR Patient must be undergoing treatment with this drug administered every four weeks in cycles 10 and beyond - prescribe up to 2 repeats. Prior systemic therapy may include autologous stem cell transplant. Definition of patients unable to receive treatment with CAR-T cell therapy for this condition include geographical, psychosocial, clinical ineligibility or urgency.	
C16466		Epcoritamab	Relapsed or refractory diffuse large B-cell lymphoma (DLBCL) Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be discontinued in patients who experience disease progression whilst on treatment. Patient must be undergoing treatment with this drug administered weekly in cycles 1 to 3 - prescribe up to 9 repeats; OR Patient must be undergoing treatment with this drug administered fortnightly in cycles 4 to 9 - prescribe up to 5 repeats; OR Patient must be undergoing treatment with this drug administered every four weeks in cycles 10 and beyond - prescribe up to 2 repeats.	Compliance with Authority Required procedures - Streamlined Authority Code 16466
C16472	P16472	Amivantamab	Stage IIIB/ IIIC (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment Patient must have evidence in tumour material of an activating epidermal growth factor receptor (EGFR) exon 20 insertion mutation; AND Patient must have/have had a WHO performance status of no greater than 2 at treatment initiation with this drug for this condition; AND Patient must not have previously received this drug for this condition; OR Patient must be each of: (i) currently receiving non-PBS-subsidised supply for this drug for this PBS indication, (ii) free of disease progression since commencing non-PBS-subsidised supply; AND The treatment must be/have been in combination with platinum-based chemotherapy (PBC) where the patient has not previously received systemic therapy for this condition in the metastatic setting, (i.e. used in combination with PBC in the first line setting); OR The treatment must be the sole PBS-subsidised therapy where the condition has progressed following treatment with platinum-based chemotherapy, (i.e. used as monotherapy in the second line setting).	Compliance with Authority Required procedures

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