PB 44 of 2024

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

National Health Act 1953

I, NIKOLAI TSYGANOV, 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 29 April 2024

NIKOLAI TSYGANOV
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 2024*

(2) This instrument may also be cited as PB 44 of 2024.

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 2024*	*1 May 2024*

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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, entry for Cemiplimab

omit from the column headed "Circumstances": **C13322**

[2] Schedule 1, Part 1, entry for Daratumumab in each of the forms: Solution concentrate for I.V. infusion 100 mg in 5 mL; and Solution concentrate for I.V. infusion 400 mg in 20 mL

omit from the column headed "Circumstances": **C12844**

[3] Schedule 1, Part 1, after entry for Docetaxel in the form Solution concentrate for I.V. infusion 160 mg in 16 mL

insert:

Dostarlimab	Solution concentrate for I.V. infusion 500 mg in 10 mL	Injection	Jemperli	C15163 C15196 C15205

[4] Schedule 1, Part 2, entry for Cemiplimab *[Maximum Amount: 350 mg; Number of Repeats: 7]*

omit from the column headed "Purposes": **P13322**

[5] Schedule 1, Part 2, entry for Daratumumab

omit:

	P12844	1920 mg	7

[6] Schedule 1, Part 2, after entry for Docetaxel

insert:

Dostarlimab	P15163	500 mg	5
	P15196 P15205	1000 mg	3

[7] Schedule 2, entry for Daratumumab

omit from the column headed "Circumstances" (all instances): **C13944**

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

omit from the column headed "Purposes": **P13944**

[9] Schedule 3, Part 1, omit entry for Circumstances Code "C12844"

[10] Schedule 3, Part 1, omit entry for Circumstances Code "C13322"

[11] Schedule 3, Part 1, omit entry for Circumstances Code "C13944"

[12] Schedule 3, Part 1, after entry for Circumstances Code "C15094"

insert:

C15163	P15163	Dostarlimab	Advanced, metastatic or recurrent endometrial carcinoma Initial treatment covering the first 6 treatment cycles Patient must have deficient mismatch repair (dMMR) endometrial cancer, as determined by immunohistochemistry test; AND The condition must be unsuitable for at least one of the following: (i) curative surgical resection, (ii) curative radiotherapy; AND The treatment must be initiated in combination with platinum-containing chemotherapy; AND The condition must be, at treatment initiation with this drug, either: (i) untreated with systemic therapy, (ii) treated with neoadjuvant/adjuvant systemic therapy, but the cancer has recurred or progressed after more than 6 months from the last dose of systemic therapy; AND Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for this condition; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation.	Compliance with Authority Required procedures - Streamlined Authority Code 15163
C15196	P15196	Dostarlimab	Advanced, metastatic or recurrent endometrial carcinoma Transitioning from non-PBS to PBS-subsidised treatment - Grandfather treatment Patient must have deficient mismatch repair (dMMR) endometrial cancer, as determined by immunohistochemistry test; AND Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 May 2024; AND The condition must be, prior to initiation of non-PBS-subsidised treatment with this drug, unsuitable for at least one of the following: (i) curative surgical resection, (ii) curative radiotherapy; AND The condition must be, prior to initiation of non-PBS-subsidised treatment with this drug, either: (i) untreated with systemic therapy, (ii) treated with neoadjuvant/adjuvant systemic therapy, but the cancer has recurred or progressed after more than 6 months from the last dose of systemic	Compliance with Authority Required procedures - Streamlined Authority Code 15196

			therapy; AND Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation; AND The treatment must be, at initiation of non-PBS-subsidised treatment with this drug, used in combination with platinum-containing chemotherapy; AND Patient must not have developed disease progression while receiving non-PBS-subsidised treatment with this drug for this condition. Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 36 cumulative months from the first administered dose, once in a lifetime.	
C15205	P15205	Dostarlimab	Advanced, metastatic or recurrent endometrial carcinoma 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 PBS-subsidised treatment with this drug for this condition. Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 36 cumulative months from the first administered dose, once in a lifetime.	Compliance with Authority Required procedures - Streamlined Authority Code 15205