PB 80 of 2024

National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment (August 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 30 July 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 (August Update) Instrument 2024*

(2) This instrument may also be cited as PB 80 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 August 2024*	*1 August 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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 Avelumab

(a) *omit from the column headed "Circumstances":* **C13313**

(b) *insert in numerical order in the column headed "Circumstances":* **C15485**

[2] Schedule 1, Part 1, entry for Durvalumab in the each of the forms: Solution concentrate for I.V. infusion 120 mg in 2.4 mL; and Solution concentrate for I.V. infusion 500 mg in 10 mL

(a) *omit from the column headed "Circumstances":* **C10126**

(b) *insert in numerical order in the column headed "Circumstances":* **C15500**

[3] Schedule 1, Part 1, entry for Mitozantrone

omit:

Injection 25 mg (as hydrochloride) in 12.5 mL	Injection	Onkotrone

[4] Schedule 1, Part 1, entry for Nivolumab in each of the forms: Injection concentrate for I.V. infusion 40 mg in 4 mL; and Injection concentrate for I.V. infusion 100 mg in 10 mL

insert in numerical order in the column headed "Circumstances": **C15471 C15527**

[5] Schedule 1, Part 2, entry for Avelumab *[Maximum Amount: 800 mg; Number of Repeats: 7]*

omit from the column headed "Purposes": **P13313** *substitute:* **P15485**

[6] Schedule 1, Part 2, entry for Durvalumab *[Maximum Amount: 1500 mg; Number of Repeats: 4]*

(a) *omit from the column headed "Purposes":* **P10126**

(b) *insert in numerical order in the column headed "Purposes":* **P15500**

[7] Schedule 1, Part 2, after entry for Nivolumab *[Maximum Amount: 120 mg; Number of Repeats: 3]*

insert:

P15471	360 mg	2

[8] Schedule 1, Part 2, entry for Nivolumab *[Maximum Amount: 480 mg; Number of Repeats: 5]*

insert in numerical order in the column headed "Purposes": **P15527**

[9] Schedule 2, after entry for Aprepitant *[Brand: APREPITANT SCP]*

insert:

Atezolizumab	Solution for subcutaneous injection 1875 mg in 15 mL	Injection	Tecentriq SC	C10125 C10206 C10216 C10297 C10521 C10939 C13443 C13448 C15455	P10206 P10939	1	3
				C10125 C10206 C10216 C10297 C10521 C10939 C13443 C13448 C15455	P10521	1	4
				C10125 C10206 C10216 C10297 C10521 C10939 C13443 C13448 C15455	P10125 P13443 P13448	1	5
				C10125 C10206 C10216 C10297 C10521 C10939 C13443 C13448 C15455	P10216 P10297 P15455	1	7

[10] Schedule 2, entry for Folinic acid

omit:

	Injection containing calcium folinate equivalent to 100 mg folinic acid in 10 mL	Injection	Leucovorin Calcium (Pfizer Australia Pty Ltd)			10	1

[11] Schedule 3, Part 1, omit entry for Circumstances Code "C10126"

[12] Schedule 3, Part 1, omit entry for Circumstances Code "C13313"

[13] Schedule 3, Part 1, after entry for Circumstances Code "C15205"

insert:

C15455	P15455	Atezolizumab	Resected early stage (Stage II to IIIA) non-small cell lung cancer (NSCLC) 1,875 mg administered once every 3 weeks Patient must be both: (i) initiating treatment, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy; OR Patient must be continuing existing PBS-subsidised treatment with this drug; OR Patient must be both: (i) transitioning from existing non-PBS to PBS subsidised supply of this drug, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy at the time this drug was initiated. Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug. The treatment must be for the purpose of adjuvant therapy following all of: (i) surgical resection, (ii) platinum-based chemotherapy; AND The condition must have/have had, at treatment commencement, an absence of each of the following gene abnormalities confirmed via tumour material sampling: (i) an activating epidermal growth factor receptor (EGFR) gene mutation, (ii) an anaplastic lymphoma kinase (ALK) gene rearrangement; AND The condition must have/have had, at treatment commencement, confirmation of programmed cell death ligand 1 (PD-L1) expression on at least 50% of tumour cells; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition. Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 12 months in total for this condition from the first administered dose; mark any remaining repeat prescriptions with the words 'cancelled' where (i)/(ii) has occurred.	Compliance with Authority Required procedures - Streamlined Authority Code 15455
C15471	P15471	Nivolumab	Resectable non-small cell lung cancer (NSCLC) The condition must be at least one of: (i) node positive, (ii) at least 4 cm in size; AND The treatment must be for neoadjuvant use in a patient preparing for surgical resection; AND Patient must have a WHO performance status of 0 or 1; AND The treatment must be in combination with platinum-based chemotherapy. Patient must not be undergoing treatment with more than 3 PBS-subsidised doses of this drug per lifetime for this indication. In non-squamous type NSCLC where any of the following is known to be present, this drug must not be a PBS benefit: (i) activating epidermal growth factor receptor (EGFR) gene mutation, (ii) anaplastic lymphoma kinase (ALK) gene rearrangement.	Compliance with Authority Required procedures - Streamlined Authority Code 15471
C15485	P15485	Avelumab	Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer	Compliance with Authority Required

			Maintenance therapy - Initial treatment Patient must have received first-line platinum-based chemotherapy; AND Patient must not have progressive disease following first-line platinum-based chemotherapy; AND Patient must have a WHO performance status of 0 or 1; AND The treatment must be the sole PBS-subsidised therapy for this condition; 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.	procedures - Streamlined Authority Code 15485
C15500	P15500	Durvalumab	Unresectable Stage III non-small cell lung cancer Initial treatment Patient must have received platinum based chemoradiation therapy; AND The condition must not have progressed following platinum based chemoradiation therapy; AND Patient must have a WHO performance status of 0 or 1; AND Patient must be untreated with immunotherapy at commencement of this drug; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 15500
C15527	P15527	Nivolumab	Urothelial carcinoma The treatment must be for each of: (i) adjuvant therapy that is/was initiated within 120 days of radical surgical resection, (ii) muscle invasive type disease, (iii) disease considered to be at high risk of recurrence based on pathologic staging of radical surgery tissue (ypT2-ypT4a or ypN+), but yet to recur, (iv) use as the sole PBS-subsidised anti-cancer treatment for this condition; AND Patient must have received prior platinum containing neoadjuvant chemotherapy; AND Patient must have/have had, at the time of initiating treatment with this drug, a WHO performance status no higher than 1. Patient must be undergoing treatment with a dosing regimen as set out in the drug's Therapeutic Goods Administration (TGA) approved Product Information; AND Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 12 months in total for this condition from the first administered dose; mark any remaining repeat prescriptions with the words 'cancelled' where (i)/(ii) has occurred. An increase in repeat prescriptions, up to a value of 11, may only be sought where the prescribed dosing is 240 mg administered fortnightly.	Compliance with Authority Required procedures