PB 117 of 2023

National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2023 (No. 11)

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*.

Date 30 November 2023

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 Instrument 2023 (No. 11)*

(2) This instrument may also be cited as PB 117 of 2023.

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 December 2023*	*1 December 2023*

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 2011 (PB 79 of 2011)

[1] Schedule 1, Part 1, entry for Carboplatin

omit:

			DBL Carboplatin	PF	MP		D

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

substitute:

Cyclophosphamide	Powder for injection 500 mg (anhydrous)	Injection	CYCLOPHOSPHAMID E-REACH	RQ	MP		PB
			Endoxan	BX	MP		PB
	Powder for injection 1 g (anhydrous)	Injection	CYCLOPHOSPHAMID E-REACH	RQ	MP		PB
			Endoxan	BX	MP		PB
	Powder for injection 2 g (anhydrous)	Injection	Endoxan	BX	MP		PB

[3] Schedule 1, Part 1, entry for Durvalumab in 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

omit from the column headed "Circumstances": **C10126 C12271** *substitute:* **C10126 C10206 C10509 C12271 C14708**

[4] Schedule 1, Part 1, entry for Fluorouracil in the form Injection 2500 mg in 50 mL

omit:

			DBL Fluorouracil Injection BP	PF	MP	C6266 C6297	D

[5] **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**

(a) *omit from the column headed "Circumstances":* **C13888**

(b) *insert in numerical order in the column headed "Circumstances":* **C14676**

[6] **Schedule 1, Part 1, entry for Oxaliplatin in the form Solution concentrate for I.V. infusion 100 mg in 20 mL**

omit:

	DBL Oxaliplatin Concentrate	PF	MP	D

[7] **Schedule 1, Part 1, entry for Pembrolizumab**

insert in numerical order in the column headed "Circumstances": **C14727**

[8] **Schedule 1, Part 1, entry for Pemetrexed in each of the forms: Powder for I.V. infusion 100 mg (as disodium); and Powder for I.V. infusion 500 mg (as disodium)**

omit:

	Pemetrexed-AFT	AE	MP	D

[9] **Schedule 1, Part 2, entry for Durvalumab**

substitute:

Durvalumab	P10206	1500 mg	3
	P10126 P12271	1500 mg	4
	P10509 P14708	1500 mg	5

[10] **Schedule 1, Part 2, entry for Nivolumab *[Maximum Amount: 480 mg; Number of Repeats: 13]***

omit from the column headed "Purposes": **P13888** *substitute:* **P14676**

[11] **Schedule 1, Part 2, after entry for Pembrolizumab *[Maximum Amount: 400 mg; Number of Repeats: 6]***

insert:

P14727	400 mg	7

[12] Schedule 2, entry for Ondansetron

omit:

Wafer 8 mg	Oral	Zofran Zydis	AS	MP	C5743	4	0	C

[13] Schedule 4, entry for Durvalumab

substitute:

Durvalumab	C10126	P10126	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 not have previously received PBS-subsidised treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 10126
	C10206	P10206	Extensive-stage small cell lung cancer Initial treatment The condition must be previously untreated; AND Patient must have a WHO performance status of 0 or 1; AND The treatment must be in combination with etoposide and a platinum-based antineoplastic drug.	Compliance with Authority Required procedures - Streamlined Authority Code 10206
	C10509	P10509	Extensive-stage small cell lung cancer Continuing treatment - 4 weekly treatment regimen The treatment must be as monotherapy; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not have developed disease progression while being treated with this drug for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 10509
	C12271	P12271	Unresectable Stage III non-small cell lung cancer 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 being treated with this drug for this condition; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND The treatment must not exceed 12 months in total for this condition under the initial and continuing restriction combined; AND The treatment must be once in a lifetime with this drug for this condition.	Compliance with Authority Required procedures - Streamlined Authority Code 12271
	C14708	P14708	Locally advanced, metastatic or recurrent biliary tract cancer (intrahepatic cholangiocarcinoma, extrahepatic	Compliance with

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			cholangiocarcinoma, and gallbladder cancer) Patient must have either of the following at treatment initiation: (i) locally advanced biliary tract cancer that is untreated with systemic anti-cancer therapy in the unresectable setting, (ii) metastatic biliary tract cancer that is untreated with systemic anti-cancer therapy in the metastatic setting. 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/have been initiated with both: (i) gemcitabine, (ii) cisplatin (refer to Product Information of gemcitabine and cisplatin for dosing information); AND Patient must not have developed disease progression while being treated with this drug for this condition.	Authority Required procedures - Streamlined Authority Code 14708

[14] Schedule 4, entry for Nivolumab

(a) *omit:*

	C13888	P13888	Advanced or metastatic gastro-oesophageal cancers The condition must be a gastro-oesophageal cancer type as specified in the drug's 'Indications' section of the approved Australian Product Information; AND The treatment must be prescribed in accordance with the drug's 'Indications' section of the approved Australian Production Information with respect to each of: (i) concomitant drugs/therapies, (ii) line of therapy (i.e. prior treatments, if any); AND Patient must have/have had, at the time of initiating treatment with this drug, a WHO performance status no higher than 1; AND Patient must be untreated with programmed cell death-1/ligand-1 (PD-1/PD-L1) inhibitor therapy for gastro-oesophageal cancer. Patient must not be undergoing treatment with this drug as a PBS benefit where the treatment duration extends beyond the following, whichever comes first: (i) disease progression despite treatment with this drug, (ii) 24 months from treatment initiation; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs.	Compliance with Authority Required procedures - Streamlined Authority Code 13888

(b) *insert in numerical order after existing text:*

	C14676	P14676	Advanced or metastatic gastro-oesophageal cancers Patient must have/have had, at the time of initiating treatment with this drug, a WHO performance status no higher than 1; AND Patient must be untreated (up until initiating this drug) with programmed cell death-1/ligand-1 (PD-1/PD-L1) inhibitor therapy for gastro-oesophageal cancer. Patient must not be undergoing treatment with this drug as a PBS benefit where the treatment duration extends beyond the following, whichever comes first: (i) disease progression despite treatment with this drug, (ii) 24 months from treatment initiation; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs. Patient must be in one of the three population subsets described below. Population 1 Conditions: gastric cancer, gastro-oesophageal junction cancer, oesophageal adenocarcinoma Concomitant therapies: chemotherapy containing at least a fluoropyrimidine drug plus a platinum drug	Compliance with Authority Required procedures - Streamlined Authority Code 14676

			Line of treatment: first-line drug treatment Additional clinical finding: HER2 negative Population 2 Condition: oesophageal squamous cell carcinoma (can be recurrent) Concomitant therapies: chemotherapy containing at least a fluoropyrimidine drug plus a platinum drug Line of treatment: first-line drug treatment Additional clinical finding: unresectable Population 3 Condition: oesophageal squamous cell carcinoma (can be recurrent) Line of treatment: second-line drug treatment after chemotherapy containing at least a fluoropyrimidine drug plus a platinum drug Additional clinical finding: unresectable	

[15] Schedule 4, entry for Pembrolizumab

insert in numerical order after existing text:

	C14727	P14727	Stage II or Stage III triple negative breast cancer The treatment must be initiated in combination with neoadjuvant chemotherapy; AND The condition must not have progressed/recurred whilst on treatment with this drug. Patient must not be undergoing treatment with this drug beyond 52 cumulative weeks under this restriction; AND Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 7 repeat prescriptions; OR Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 4 repeat prescriptions.	Compliance with Authority Required procedures - Streamlined Authority Code 14727

[16] Schedule 5

repeal the table and substitute:

Listed Drug	Form	Manner of Administration	Brand	Quantity or Number of Units	Approved Ex-manufacturer Price	Claimed Ex-manufacturer Price

Note: There are currently no pharmaceutical benefits mentioned in Schedule 5.

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