PB 47 of 2023

National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2023 (No. 5)

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 May 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. 5)*

(2) This instrument may also be cited as PB 47 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 June 2023*	*1 June 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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 Bortezomib in the form Powder for injection 3.5 mg

omit:

	Bortezomib-Dr.Reddy's	RI	MP	C11099 C13745		D

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

insert in numerical order in the column headed "Circumstances": **C14027 C14028 C14044**

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

insert in numerical order in the column headed "Purposes": **P14027 P14028 P14044**

[4] Schedule 2, entry for Fosaprepitant

insert in the columns in the order indicated, and in alphabetical order for the column headed "Brand":

	FOSAPREPITANT-AFT	AE	MP	C6852 C6886 C6887 C6891	1	5	

[5] Schedule 2, entry for Ondansetron in the form Tablet (orally disintegrating) 4 mg

omit:

	Ondansetron ODT GH	GQ	MP	C5743	4	0	C

[6] Schedule 2, entry for Ondansetron in the form Tablet (orally disintegrating) 8 mg

omit:

	Ondansetron ODT GH	GQ	MP	C5743	4	0	C

[7] Schedule 3,

omit:

GQ	Generic Health Pty Ltd	93 110 617 859

[8] Schedule 3,

omit:

RI	Dr Reddy's Laboratories (Australia) Pty Ltd	16 120 092 408

[9] Schedule 4, entry for Pembrolizumab

insert in numerical order after existing text:

	C14027	P14027	Advanced, metastatic or recurrent endometrial carcinoma Initial treatment Patient must have received prior treatment with platinum-based chemotherapy; AND The condition must be untreated with each of: (i) programmed cell death-1/ligand-1 (PD-1/PDL-1) inhibitor therapy, (ii) tyrosine kinase inhibitor 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. Patient must be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; AND Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.	Compliance with Authority Required procedures - Streamlined Authority Code 14027
	C14028	P14028	Advanced, metastatic or recurrent endometrial carcinoma Transitioning from non-PBS to PBS-subsided supply - Grandfather arrangements Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 June 2023; AND The treatment must be occurring in a patient where each of the following is true: (i) the patient had received prior treatment with platinum-based chemotherapy, (ii) the patient was untreated at treatment initiation with each of: (a) programmed cell death-1/ligand-1 (PD-1/PDL-1) inhibitor therapy, (b) tyrosine kinase inhibitor therapy, (iii) the patient's WHO performance status was no higher than 1 at treatment initiation, (iv) this drug is being prescribed in either: (a) a combination of pembrolizumab plus lenvatinib only, (b) as monotherapy where there was a contraindication/intolerance to the other drug in the combination - document the details in the patient's medical records, (v) disease progression has not occurred whilst on treatment, (vi) this prescription does not extend treatment beyond 24 months from the first administered dose. Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe	Compliance with Authority Required procedures - Streamlined Authority Code 14028

			up to 3 repeat prescriptions.	
	C14044	P14044	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 be undergoing combination therapy consisting of: (i) pembrolizumab, (ii) lenvatinib; OR Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to the other drug in the combination mentioned above, requiring temporary/permanent discontinuation; document the details in the patient's medical records; AND Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 6 repeat prescriptions; OR Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions; AND Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime.	Compliance with Authority Required procedures - Streamlined Authority Code 14044