



PB 133 of 2023

National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2023 (No. 12)

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 21 December 2023

NIKOLAI TSYGANOV
Assistant Secretary
Pricing and PBS Policy Branch
Technology Assessment and Access Division

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1 Name

- (1) This instrument is the *National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2023 (No. 12)*
- (2) This instrument may also be cited as PB 133 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. <i>The whole of this instrument</i>	<i>1 January 2024</i>	<i>1 January 2024</i>

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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-AFT	AE	MP	C11099 C13745	D
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[2] Schedule 1, Part 1, entry for Obinutuzumab

insert in numerical order in the column headed "Circumstances": C14764

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

(a) *omit from the column headed "Circumstances": C10687*

(b) *omit from the column headed "Circumstances": C10695*

(c) *insert in numerical order in the column headed "Circumstances: C14770 C14786*

[4] Schedule 1, Part 2, entry for Obinutuzumab [*Maximum Amount: 1000 mg; Number of Repeats: 5*]

insert in numerical order in the column headed "Purposes": P14764

[5] Schedule 1, Part 2, entry for Pembrolizumab [*Maximum Amount: 200 mg; Number of Repeats: 7*]

(a) *omit from the column headed "Purposes": P10687 P10695*

(b) *insert in numerical order in the column headed "Purposes": P14770 P14786*

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

omit:

	APO-Ondansetron ODT	TX	MP	C5743	4	0	C
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[7] Schedule 2, entry for Ondansetron in the form Tablet 4 mg (as hydrochloride dihydrate)

omit:

	Ondansetron	GX	MP	C5778	4	0	C
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APOTEX

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

omit:

APO-Ondansetron ODT	TX	MP	C5743	4	0	C
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[9] Schedule 2, entry for Ondansetron in the form Tablet 8 mg (as hydrochloride dihydrate)

omit:

Ondansetron APOTEX	GX	MP	C5778	4	0	C
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[10] Schedule 3

omit:

GX	Apotex Pty Ltd	52 096 916 148
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[11] Schedule 4, entry for Obinutuzumab

insert in numerical order after existing text:

C14764	P14764	Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL) For combination use with acalabrutinib from treatment cycles 2 to 7 inclusive in first-line therapy The condition must be untreated; AND The treatment must be in combination with PBS-subsidised acalabrutinib (refer to Product Information for timing of obinutuzumab and acalabrutinib doses).	Compliance with Authority Required procedures - Streamlined Authority Code 14764
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[12] Schedule 4, entry for Pembrolizumab

(a) *omit:*

C10687	P10687	Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma Initial treatment - 3 weekly treatment regimen The treatment must be adjuvant to complete surgical resection; AND Patient must have a WHO performance status of 1 or less; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not have received prior PBS-subsidised treatment for this condition; AND The treatment must commence within 12 weeks of complete resection; AND Patient must not receive more than 12 months of combined PBS-subsidised and	Compliance with Authority Required procedures
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non-PBS-subsidised adjuvant therapy.

(b) *omit:*

C10695	P10695	Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma Continuing treatment - 3 weekly treatment regimen Patient must have previously been issued with an authority prescription for this drug for adjuvant treatment following complete surgical resection; AND Patient must not have experienced disease recurrence; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.	Compliance with Authority Required procedures
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(c) *insert in numerical order after existing text:*

C14770	P14770	Stage IIIB, Stage IIIC or Stage IIID malignant melanoma Initial treatment - 3 weekly treatment regimen The treatment must be in addition to complete surgical resection; AND Patient must have a WHO performance status of 1 or less; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not have received prior PBS-subsidised treatment for this condition; AND The treatment must commence within 12 weeks of complete resection; AND Patient must not have received more than 12 months of therapy (irrespective of whether therapy has been partly PBS-subsidised/non-PBS-subsidised).	Compliance with Authority Required procedures
C14786	P14786	Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma Continuing treatment - 3 weekly treatment regimen Patient must be undergoing continuing PBS-subsidised treatment commenced through an 'Initial treatment' listing. Patient must not have experienced disease recurrence; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not have received more than 12 months of therapy (irrespective of whether therapy has been partly PBS-subsidised/non-PBS-subsidised).	Compliance with Authority Required procedures