



PB 72 of 2023

National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2023 (No. 7)

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 27 July 2023

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

Contents

1	Name	1
2	Commencement	1
3	Authority.....	1
4	Schedules	1
Schedule 1—Amendments		2
	<i>National Health (Efficient Funding of Chemotherapy) Special Arrangement 2011 (PB 79 of 2011)</i>	2

1 Name

- (1) This instrument is the *National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2023 (No. 7)*
- (2) This instrument may also be cited as PB 72 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 August 2023</i>	<i>1 August 2023</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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 Bendamustine

substitute:

Bendamustine	Powder for injection containing bendamustine hydrochloride 25 mg	Injection	Bendamustine Sandoz	SZ	MP	C7943 C7944 C7972	D
			Bendamustine Viatris	AF	MP	C7943 C7944 C7972	D
			Ribomustin	JC	MP	C7943 C7944 C7972	D
	Powder for injection containing bendamustine hydrochloride 100 mg	Injection	Bendamustine Sandoz	SZ	MP	C7943 C7944 C7972	D
			Bendamustine Viatris	AF	MP	C7943 C7944 C7972	D
			Ribomustin	JC	MP	C7943 C7944 C7972	D

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

omit:

	Solution for injection containing epirubicin hydrochloride 50 mg in 25 mL	Injection/intravesical	Epirubicin	TB	MP		D
--	---	------------------------	------------	----	----	--	---

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

omit:

	Solution concentrate for I.V. infusion 100 mg in 16.7 mL	Injection	Paclitaxin	TB	MP		D
	Solution concentrate for I.V. infusion 150 mg in 25 mL	Injection	Paclitaxin	TB	MP		D

[4] Schedule 1, Part 1, after entry for Topotecan in the form Solution concentrate for I.V. infusion 4 mg in 4 mL (as hydrochloride)

insert:

Trabectedin	Powder for I.V. infusion 1 mg	Injection	Yondelis	ZL	MP	C14188 C14196 C14197	D
-------------	-------------------------------	-----------	----------	----	----	-------------------------	---

[5] Schedule 1, Part 2, after entry for Topotecan

insert:

Trabectedin	P14196	3250	3
	P14188 P14197	3250	7

[6] Schedule 3, after details relevant to Responsible Person code XC

insert:

ZL	Specialised Therapeutics Pharma Pty Ltd	77 609 261 430
----	---	----------------

[7] Schedule 4, after entry for Sacituzumab govitecan

insert:

Trabectedin	C14188	P14188	Advanced (unresectable and/or metastatic) leiomyosarcoma or liposarcoma Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements Patient must have been receiving treatment with this drug for this condition prior to 1 August 2023; AND Patient must have had a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 2 at the time non-PBS supply was initiated; AND Patient must have received chemotherapy treatment including an anthracycline, prior to initiating non-PBS-subsidised treatment; AND Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND The condition must be one of the following subtypes for patients with liposarcoma: (i) dedifferentiated, (ii) myxoid, (iii) round-cell, (iv) pleomorphic. This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.	Compliance with Authority Required procedures - Streamlined Authority Code 14188
	C14196	P14196	Advanced (unresectable and/or metastatic) leiomyosarcoma or liposarcoma Initial treatment Patient must have an ECOG performance status of 2 or less; AND Patient must have received prior chemotherapy treatment including an anthracycline; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition; AND The condition must be one of the following subtypes for patients with liposarcoma: (i) dedifferentiated, (ii) myxoid, (iii) round-cell, (iv) pleomorphic.	Compliance with Authority Required procedures - Streamlined Authority Code 14196

		This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.	
C14197	P14197	<p>Advanced (unresectable and/or metastatic) leiomyosarcoma or liposarcoma 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 treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition. This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 14197</p>