PB 6 of 2024

National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2024 (No. 1)

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 31 January 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 Instrument 2024 (No. 1)*

(2) This instrument may also be cited as PB 6 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 February 2024*	*1 February 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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 2011 (PB 79 of 2011)

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

omit:

	CIPLA BLEOMYCIN	LR	MP	C6224 C6275	D

[2] Schedule 1, Part 1, entry for Ipilimumab in each of the forms: Injection concentrate for I.V. infusion 50 mg in 10 mL; and Injection concentrate for I.V. infusion 200 mg in 40 mL

(a) *omit from the column headed "Circumstances":* **C13841**

(b) *insert in numerical order in the column headed "Circumstances":* **C14808**

[3] Schedule 1, Part 1, entry for Irinotecan in each of the forms: I.V. injection containing irinotecan hydrochloride trihydrate 40 mg in 2 mL; and I.V. injection containing irinotecan hydrochloride trihydrate 100 mg in 5 mL

omit:

	MEDITAB IRINOTECAN	LR	MP		D

[4] Schedule 1, Part 1, entry for Methotrexate in the form Solution concentrate for I.V. infusion 1000 mg in 10 mL vial

omit:

	Pfizer Australia Pty Ltd	PF	MP		PB

[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":* **C10155**

(b) *omit from the column headed "Circumstances":* **C13853**

(c) *insert in numerical order in the column headed "Circumstances":* **C14816 C14830**

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

(a) *omit from the column headed "Circumstances":* **C10689 C10696**

(b) *insert in numerical order in the column headed "Circumstances":* **C14817 C14818**

[7] Schedule 1, Part 1, after entry for Sacituzumab govitecan

insert:

Tebentafusp	Solution concentrate for I.V. infusion 100 micrograms in 0.5 mL	Injection	Kimmtrak	WM	MP	C14813 C14821 C14822 C14825	D

[8] Schedule 1, Part 2, entry for Ipilimumab *[Maximum Amount: 360 mg; Number of Repeats: 3]*

(a) *omit from the column headed "Purposes":* **P13841**

(b) *insert in numerical order in the column headed "Purposes":* **P14808**

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

(a) *omit from the column headed "Purposes":* **P13853**

(b) *insert in numerical order in the column headed "Purposes":* **P14830**

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

(a) *omit from the column headed "Purposes":* **P10155**

(b) *insert in numerical order in the column headed "Purposes":* **P14816**

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

omit from the column headed "Purposes": **P10696** *substitute:* **P14818**

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

omit from the column headed "Purposes": **P10689** *substitute:* **P14817**

[13] Schedule 1, Part 2, after entry for Sacituzumab govitecan *[Maximum Amount: 1200 mg; Number of Repeats: 13]*

insert:

Tebentafusp	P14813	20 mcg	0
	P14821	30 mcg	0

P14825	68 mcg	0
P14822	136 mcg	7

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

omit:

	Ondansetron AN ODT	EA	MP	C5743	4	0	C

[15] Schedule 2, entry for Ondansetron in the form Tablet 4 mg (as hydrochloride dihydrate)

omit:

	Ondansetron AN	EA	MP	C5778	4	0	C

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

omit:

	Ondansetron AN ODT	EA	MP	C5743	4	0	C

[17] Schedule 2, entry for Ondansetron in the form Tablet 8 mg (as hydrochloride dihydrate)

omit:

	Ondansetron AN	EA	MP	C5778	4	0	C

[18] Schedule 2, entry for Palonosetron

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

	PALONOSETRON Medsurge	DZ	MP	C5805	1	0	C

[19] Schedule 3, after details relevant to Responsible Person code CR

insert:

DZ	Medsurge Healthcare Pty Ltd	92 124 728 892

[20] Schedule 3

omit:

EA	Amneal Pharmaceuticals Pty Ltd	11 163 167 851

[21] Schedule 3, after details relevant to Responsible Person code TY

insert:

WM	MEDISON PHARMA AUSTRALIA PTY LIMITED	19 659 723 403

[22] Schedule 4, entry for Ipilimumab

(a) *omit:*

	C13841	P13841	Unresectable Stage III or Stage IV malignant melanoma Induction treatment Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; AND Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; AND The condition must not be ocular or uveal melanoma; AND The treatment must be in combination with PBS-subsidised treatment with nivolumab as induction therapy for this condition. Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks. Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.	Compliance with Authority Required procedures - Streamlined Authority Code 13841

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

	C14808	P14808	Unresectable Stage III or Stage IV malignant melanoma Induction treatment Patient must not have received prior treatment with nivolumab plus relatlimab, ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; AND Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; AND The condition must not be ocular or uveal melanoma; AND The treatment must be in combination with PBS-subsidised treatment with nivolumab as induction therapy for this condition. Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 1	Compliance with Authority Required procedures - Streamlined Authority Code 14808

			mg per kg every 3 weeks. Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks. The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.	

[23] Schedule 4, entry for Nivolumab

(a) *omit:*

	C10155	P10155	Unresectable Stage III or Stage IV malignant melanoma Initial treatment Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; AND Patient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIB, IIIC, IIID or IV melanoma; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.	Compliance with Authority Required procedures - Streamlined Authority Code 10155

(b) *omit:*

	C13853	P13853	Unresectable Stage III or Stage IV malignant melanoma Induction treatment Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; AND Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; AND The condition must not be ocular or uveal melanoma; AND The treatment must be in combination with PBS-subsidised treatment with ipilimumab as induction for this condition. Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks. Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.	Compliance with Authority Required procedures - Streamlined Authority Code 13853

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

	C14816	P14816	Unresectable Stage III or Stage IV malignant melanoma Initial treatment Patient must not have received prior treatment with nivolumab plus relatlimab, ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; AND	Compliance with Authority Required procedures - Streamlined Authority Code 14816

			Patient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIB, IIIC, IIID or IV melanoma; AND The treatment must be the sole PBS-subsidised therapy for this condition. Patients must only receive a maximum of 240 mg every two weeks or 480 mg every four weeks under a weight based or flat dosing regimen.	
	C14830	P14830	Unresectable Stage III or Stage IV malignant melanoma Induction treatment Patient must not have received prior treatment with nivolumab plus relatlimab, ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; AND Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; AND The condition must not be ocular or uveal melanoma; AND The treatment must be in combination with PBS-subsidised treatment with ipilimumab as induction for this condition. Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks. Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.	Compliance with Authority Required procedures - Streamlined Authority Code 14830

[24] Schedule 4, entry for Pembrolizumab

(a) *omit:*

	C10689	P10689	Unresectable Stage III or Stage IV malignant melanoma Initial treatment - 6 weekly treatment regimen Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; AND Patient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIB, IIIC, IIID or IV melanoma; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND The treatment must not exceed a total of 3 doses under this restriction.	Compliance with Authority Required procedures - Streamlined Authority Code 10689
	C10696	P10696	Unresectable Stage III or Stage IV malignant melanoma Initial treatment - 3 weekly treatment regimen Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; AND Patient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIB, IIIC, IIID or IV melanoma; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND	Compliance with Authority Required procedures - Streamlined Authority Code 10696

			The treatment must not exceed a total of 6 doses under this restriction.	

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

	C14817	P14817	Unresectable Stage III or Stage IV malignant melanoma Initial treatment - 6 weekly treatment regimen Patient must not have received prior treatment with nivolumab plus relatlimab, ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; AND Patient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIB, IIIC, IIID or IV melanoma; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND The treatment must not exceed a total of 3 doses under this restriction.	Compliance with Authority Required procedures - Streamlined Authority Code 14817
	C14818	P14818	Unresectable Stage III or Stage IV malignant melanoma Initial treatment - 3 weekly treatment regimen Patient must not have received prior treatment with nivolumab plus relatlimab, ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma; AND Patient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIB, IIIC, IIID or IV melanoma; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND The treatment must not exceed a total of 6 doses under this restriction.	Compliance with Authority Required procedures - Streamlined Authority Code 14818

[25] Schedule 4, after entry for Sacituzumab govitecan

insert:

Tebentafusp	C14813	P14813	Advanced (unresectable or metastatic) uveal melanoma Initial treatment - day 1 Patient must have HLA-A*02:01-positive disease; AND Patient must have uveal melanoma that has been confirmed either (i) histologically, (ii) cytologically; AND The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must not have received prior systemic therapy for metastatic disease. Patient must be at least 18 years of age. According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 doses (on Days 1, 8 and 15) and for at least 16 hours after each infusion is completed. If the patient does not experience hypotension that is Grade 2 or worse (requiring medical intervention) with the third dose, subsequent doses can be administered in an appropriate outpatient/ambulatory care setting. Supervision by a health care professional is recommended for a minimum of 30 minutes following each infusion. This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting. Positive HLA-A*02:01 assessment must be documented in the patient's medical records.	Compliance with Authority Required procedures

	C14821	P14821	Advanced (unresectable or metastatic) uveal melanoma Initial treatment - day 8 Patient must have HLA-A*02:01-positive disease; AND Patient must have previously received PBS-subsidised initial day 1 treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition. According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 doses (on Days 1, 8 and 15) and for at least 16 hours after each infusion is completed. If the patient does not experience hypotension that is Grade 2 or worse (requiring medical intervention) with the third dose, subsequent doses can be administered in an appropriate outpatient/ambulatory care setting. Supervision by a health care professional is recommended for a minimum of 30 minutes following each infusion. This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting. Positive HLA-A*02:01 assessment must be documented in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 14821
	C14822	P14822	Advanced (unresectable or metastatic) uveal melanoma Continuing treatment The treatment must be the sole PBS-subsidised therapy for this condition; AND Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND Patient must not receive PBS-subsidised treatment with this drug for this condition if it is no longer determined to be clinically beneficial by the treating clinician. According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 doses (on Days 1, 8 and 15) and for at least 16 hours after each infusion is completed. If the patient does not experience hypotension that is Grade 2 or worse (requiring medical intervention) with the third dose, subsequent doses can be administered in an appropriate outpatient/ambulatory care setting. Supervision by a health care professional is recommended for a minimum of 30 minutes following each infusion.	Compliance with Authority Required procedures - Streamlined Authority Code 14822
	C14825	P14825	Advanced (unresectable or metastatic) uveal melanoma Initial treatment - day 15 Patient must have HLA-A*02:01-positive disease; AND Patient must have previously received PBS-subsidised initial day 8 treatment with this drug for this condition; AND The treatment must be the sole PBS-subsidised therapy for this condition. According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 doses (on Days 1, 8 and 15) and for at least 16 hours after each infusion is completed. If the patient does not experience hypotension that is Grade 2 or worse (requiring medical intervention) with the third dose, subsequent doses can be administered in an appropriate outpatient/ambulatory care setting. Supervision by a health care professional is recommended for a minimum of 30 minutes following each infusion. This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting. Positive HLA-A*02:01 assessment must be documented in the patient's medical records.	Compliance with Authority Required procedures - Streamlined Authority Code 14825