



PB 128 of 2024

National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment (December Update) Instrument 2024

National Health Act 1953

I, EDEN SIMON, Assistant Secretary (Acting), 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*.

Dated 28 November 2024

EDEN SIMON

Assistant Secretary (Acting)
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 (December Update) Instrument 2024*
- (2) This instrument may also be cited as PB 128 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. <i>The whole of this instrument</i>	<i>1 December 2024</i>	<i>1 December 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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 2024 (PB 31 of 2024)

[1] **Part 1, Section 5 Definitions**

Insert in alphabetical order:

active ingredient, in relation to a chemotherapy drug, means a drug that is mentioned in the name of the chemotherapy drug.

Note: A chemotherapy drug may be a medicinal preparation containing multiple drugs (see the definition of ***listed drug*** in Part VII of the Act).

[2] **Part 2, Division 2, Subsection 14(2)**

Before “in relation to”, insert “(the ***maximum amount column***)”.

[3] **Part 2, Division 2, Subsection 14(3)**

Omit ‘column of the table in Part 2 of Schedule 1 headed “Maximum Amount” in relation to’, substitute ‘maximum amount column in relation to’.

[4] **At the end of Part 2, Division 2, Section 14**

Add:

(4) For a chemotherapy drug mentioned in column 1 of an item of the following table:

- (a) an amount mentioned in the maximum amount column in relation to the chemotherapy drug is the maximum amount, of the active ingredient mentioned in column 2 of the item of the following table, that an authorised prescriber may direct to be supplied in a dose of the chemotherapy drug; and
- (b) a reference in this instrument to the maximum amount of the chemotherapy drug is taken to be a reference to the maximum amount of the active ingredient.

Maximum amounts for chemotherapy drugs with multiple active ingredients		
Item	Column 1	Column 2
	Chemotherapy drug	Active ingredient
1	daunorubicin with cytarabine	daunorubicin
2	nivolumab with relatlimab	nivolumab

Item	Column 1	Column 2
	Chemotherapy drug	Active ingredient
1	daunorubicin with cytarabine	daunorubicin
2	nivolumab with relatlimab	nivolumab

[5] After Part 2, Division 2, Section 14

Insert:

14A Prescribing amounts of active ingredients in dose of chemotherapy drug

In a chemotherapy prescription for a dose of any of the following chemotherapy drugs, the amounts of each active ingredient directed to be supplied must be in the same proportion as the proportion of the active ingredients in the form of a chemotherapy pharmaceutical benefit that has that chemotherapy drug:

- (a) daunorubicin with cytarabine;
- (b) nivolumab with relatlimab.

[6] After Part 2, Division 2, Subsection 21(1)

Insert:

(1A) If the direction is for a new dose of a chemotherapy drug mentioned in section 14A, the amounts of each active ingredient in the new dose must be in the same proportion as the proportion of the active ingredients in the form of a chemotherapy pharmaceutical benefit that has that chemotherapy drug.

[7] Part 2, Division 2, Subsections 21(2) and (3)

Omit “subsection (1)”, substitute “subsections (1) and (1A)”.

[8] Schedule 1, Part 1, entry for Bortezomib in the form Powder for injection 3.5 mg

omit:

			BORTEZOMIB TEVA	C11099 C13745
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[9] Schedule 1, Part 1, after entry for Daratumumab in the form Solution concentrate for I.V. infusion 400 mg in 20 mL

insert:

Daunorubicin with cytarabine	Powder for I.V. infusion containing daunorubicin 44 mg (as hydrochloride) and cytarabine 100 mg	Injection	Vyxeos	C16187 C16197
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[10] Schedule 1, Part 1, entry for Elotuzumab in each of the forms: Powder for injection 300 mg; and Powder for injection 400 mg

omit from the column headed “Circumstances”: **C12891**

[11] Schedule 1, Part 1, after entry for Nivolumab in the form Injection concentrate for I.V. infusion 100 mg in 10 mL

insert:

Nivolumab with relatlimab	Solution concentrate for I.V. infusion containing 240 mg nivolumab and 80 mg relatlimab in 20 mL	Injection	Opdualag	C16151 C16188
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[12] Schedule 1, Part 1, entry for Trastuzumab in the form Powder for I.V. infusion 420 mg

omit from the column headed "Circumstances": C155831 substitute: C15831

[13] Schedule 1, Part 2, after entry for Daratumumab [Maximum Amount: 1920 mg; Number of Repeats: 8]

insert:

Daunorubicin with cytarabine	P16197	64 mg	3
	P16187	97 mg	4

[14] Schedule 1, Part 2, entry for Elotuzumab

omit:

	P12891	1200 mg	9
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[15] Schedule 1, Part 2, after entry for Nivolumab [Maximum Amount: 480 mg; Number of Repeats: 13]

insert:

Nivolumab with relatlimab	P16188	480 mg	8
	P16151	480 mg	11

[16] Schedule 3, Part 1, omit entry for Circumstances Code "C12891"

[17] Schedule 3, Part 1, after entry for Circumstances Code "C16085"

insert:

C16151	P16151	Nivolumab with relatlimab	Unresectable Stage III or Stage IV malignant melanoma Continuing treatment Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND	Compliance with Authority Required procedures - Streamlined Authority Code 16151
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			<p>The treatment must be the sole PBS-subsidised therapy for this condition; AND</p> <p>Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.</p> <p>Patients must only receive a maximum of 480 mg nivolumab and 160 mg relatlimab every four weeks under a flat dosing regimen.</p> <p>The prescribed dose must be according to the Therapeutic Goods Administration (TGA) Product Information.</p> <p>The prescription must include the amount of nivolumab with relatlimab (Opdualag) that is appropriate to be prescribed for the patient. For the purposes of PBS subsidy, the maximum amount requested is based on the nivolumab dose only. The prescribed amount of nivolumab must be expressed in milligrams.</p>	
C16187	P16187	Daunorubicin with cytarabine	<p>Acute Myeloid Leukaemia</p> <p>Induction therapy</p> <p>Patient must not have received prior chemotherapy as induction therapy for this condition; AND</p> <p>The condition must be either: (i) newly diagnosed therapy-related acute myeloid leukaemia (AML), (ii) newly diagnosed AML with myelodysplasia-related changes (MRC) (prior myelodysplastic syndromes (MDS) or MDS-related cytogenetic or molecular abnormality); AND</p> <p>The condition must not be either: (i) internal tandem duplication (ITD); (ii) tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3), mutation positive; AND</p> <p>Patient must not have favourable cytogenetic risk acute myeloid leukaemia (AML); AND</p> <p>Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less; AND</p> <p>The treatment must not exceed two cycles of induction therapy under this restriction.</p> <p>This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.</p> <p>The prescriber must confirm whether the patient has newly diagnosed therapy-related AML or AML-MRC. The test result and date of testing must be provided at the time of application and documented in the patient's file.</p> <p>The prescribed dose must be according to the Therapeutic Goods Administration (TGA) Product Information.</p> <p>Each prescription must include the amount of daunorubicin with cytarabine (Vyxeos) that is appropriate to be prescribed for the patient. For the purposes of the authority application, the maximum amount requested is based on the daunorubicin dose only. The prescribed amount of daunorubicin must be expressed in milligrams.</p>	Compliance with Authority Required procedures
C16188	P16188	Nivolumab with relatlimab	<p>Unresectable Stage III or Stage IV malignant melanoma</p> <p>Initial treatment</p> <p>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</p>	Compliance with Authority Required procedures - Streamlined Authority Code 16188

			<p>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</p> <p>Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; AND</p> <p>The condition must not be uveal melanoma; AND</p> <p>The treatment must be the sole PBS-subsidised therapy for this condition.</p> <p>Patient must weigh 40 kg or more; AND</p> <p>Patient must be at least 12 years of age.</p> <p>Patients must only receive a maximum of 480 mg nivolumab and 160 mg relatlimab every four weeks under a flat dosing regimen.</p> <p>The prescribed dose must be according to the Therapeutic Goods Administration (TGA) Product Information.</p> <p>The prescription must include the amount of nivolumab with relatlimab (Opdualag) that is appropriate to be prescribed for the patient. For the purposes of PBS subsidy, the maximum amount requested is based on the nivolumab dose only. The prescribed amount of nivolumab must be expressed in milligrams.</p>	
C16197	P16197	Daunorubicin with cytarabine	<p>Acute Myeloid Leukaemia</p> <p>Consolidation therapy</p> <p>The treatment must be for consolidation treatment following induction treatment with this product; AND</p> <p>The condition must be either: (i) newly diagnosed therapy-related acute myeloid leukaemia (AML), (ii) newly diagnosed AML with myelodysplasia-related changes (MRC) (prior myelodysplastic syndromes (MDS) or MDS-related cytogenetic or molecular abnormality); AND</p> <p>The treatment must not exceed two cycles of consolidation therapy under this restriction.</p> <p>This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.</p> <p>The prescribed dose must be according to the Therapeutic Goods Administration (TGA) Product Information.</p> <p>Each prescription must include the amount of daunorubicin with cytarabine (Vyxeos) that is appropriate to be prescribed for the patient. For the purposes of the authority application, the maximum amount requested is based on the daunorubicin dose only. The prescribed amount of daunorubicin must be expressed in milligrams.</p>	Compliance with Authority Required procedures