



PB 78 of 2025

National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment (July Update) Instrument 2025

National Health Act 1953

I, REBECCA RICHARDSON, Assistant Secretary, Pricing and PBS Policy Branch, Technology Assessment and Access Division, Department of Health, Disability and Ageing, delegate of the Minister for Health and Ageing, make this Instrument under subsection 100(2) of the *National Health Act 1953*.

Dated 26 June 2025

REBECCA RICHARDSON
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 (July Update) Instrument 2025*.
- (2) This instrument may also be cited as PB 78 of 2025.

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 July 2025	1 July 2025

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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] Section 5, Definition for diluent fee

omit: \$5.95 *substitute:* \$6.08

[2] Section 5, Definition for dispensing fee

omit: \$8.67 *substitute:* \$8.88

[3] Section 5, Definition for distribution fee

omit: \$30.05 *substitute:* \$30.71

[4] Section 5, Definition for preparation fee

omit: \$90.13 *substitute:* \$91.23

[5] Schedule 1, Part 1, entry for Bendamustine in each of the forms: Powder for injection containing bendamustine hydrochloride 25 mg; and Powder for injection containing bendamustine hydrochloride 100 mg

insert as first entry:

BENDAMUSTINE EUGIA	C7943 C7944 C7972
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[6] Schedule 1, Part 1, entry for Doxorubicin in the form Solution for I.V. injection or intravesical administration containing doxorubicin hydrochloride 200 mg in 100 mL single dose vial

omit:

Adriamycin

[7] Schedule 1, Part 1, entry for Irinotecan

omit:

I.V. injection containing irinotecan hydrochloride trihydrate 40 mg in 2 mL	Injection	Omegapharm Irinotecan
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[8] Schedule 1, Part 1, entry for Irinotecan in the form I.V. injection containing irinotecan hydrochloride trihydrate 100 mg in 5 mL

(a) omit:

Irinotecan Alphapharm

(b) insert after entry for the brand "IRINOTECAN BAXTER":

IRINOTECAN EUGIA

(c) omit:

Omegapharm Irinotecan

[9] Schedule 1, Part 1, entry for Irinotecan in the form I.V. injection containing irinotecan hydrochloride trihydrate 500 mg in 25 mL

(a) omit:

Irinotecan Alphapharm

(b) insert after entry for the brand "Irinotecan Accord":

IRINOTECAN EUGIA

[10] 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

insert in numerical order in the column headed "Circumstances": **C16755 C16790**

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

insert:

P16790	360 mg	5
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[12] Schedule 1, Part 2, entry for Nivolumab [**Maximum Amount: 480 mg; Number of Repeats: 5**]

insert in numerical order in the column headed "Purposes": **P16755**

[13] Schedule 3, Part 1, after entry for Circumstances Code "C16657"

insert:

C16755	P16755	Nivolumab	<p>Unresectable or metastatic urothelial carcinoma</p> <p>Continuing treatment</p> <p>Patient must have previously received up to a maximum 6 doses of combined therapy with both: (i) nivolumab, (ii) cisplatin and gemcitabine, as initial treatment for this condition; AND</p> <p>The treatment must be as monotherapy for this condition.</p> <p>Patient must be undergoing treatment with a dosing regimen as set out in the drug's Therapeutic Goods Administration (TGA) approved Product Information; AND</p> <p>Patient must not be undergoing continuing PBS-subsidised treatment where this prescription extends treatment beyond whichever comes first: (i) 24 months from treatment initiation, irrespective of whether initial treatment was PBS-subsidised/non-PBS-subsidised, (ii) disease progression despite treatment with this drug, (iii) unacceptable toxicity; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 16755</p>
C16790	P16790	Nivolumab	<p>Unresectable or metastatic urothelial carcinoma</p> <p>Initial treatment</p> <p>The condition must not have previously been treated with PBS-subsidised systemic therapy for unresectable or metastatic urothelial carcinoma; AND</p> <p>The treatment must be initiated in combination with cisplatin and gemcitabine; AND</p> <p>Patient must have/have had, at the time of initiating treatment with this drug, a WHO performance status no higher than 1; AND</p> <p>Patient must not have received prior treatment with a PBS-subsidised programmed cell death-1 (PD-1) inhibitor or programmed cell death ligand-1 (PD-L1) inhibitor for this condition.</p> <p>Patient must be undergoing treatment with a dosing regimen as set out in the drug's Therapeutic Goods Administration (TGA) approved Product Information.</p> <p>Patient must only receive up to a maximum 6 doses of PBS-subsidised combined therapy with both: (i) nivolumab, (ii) cisplatin and gemcitabine, under this PBS listing, once in a lifetime.</p>	<p>Compliance with Authority Required procedures - Streamlined Authority Code 16790</p>