PB 6 of 2025

National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment (February 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 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 30th January 2025

REBECCA RICHARDSON
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 (February Update) Instrument 2025*.

(2) This instrument may also be cited as PB 6 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 February 2025*	*1 February 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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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] Schedule 1, Part 1, entry for Paclitaxel, nanoparticle albumin-bound

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

				nab-PACLITAXEL JUNO	C4657 C6106 C6119

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

(a) *omit from the column headed "Circumstances":* **C13431**

(b) *omit from the column headed "Circumstances":* **C13436**

(c) *insert in numerical order in the column headed "Circumstances":* **C16264 C16280**

[3] Schedule 1, Part 2, entry for Pembrolizumab *[Maximum Amount: 200 mg; Number of Repeats: 6]*

(a) *omit from the column headed "Purposes":* **P13431**

(b) *insert in numerical order in the column headed "Purposes":* **P16280**

[4] Schedule 1, Part 2, entry for Pembrolizumab *[Maximum Amount: 400 mg; Number of Repeats: 3]*

(a) *omit from the column headed "Purposes":* **P13436**

(b) *insert in numerical order in the column headed "Purposes":* **P16264**

[5] Schedule 3, Part 1, omit entry for Circumstances Code "C13431"

[6] Schedule 3, Part 1, omit entry for Circumstances Code "C13436"

[7] Schedule 3, Part 1, after entry for Circumstances Code "C16197"

insert:

C16264	P16264	Pembrolizumab	Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment - 6 weekly treatment regimen Patient must not have previously been treated for this condition in the metastatic setting; OR The condition must have progressed after treatment with only one of (i) tepotinib, (ii) selpercatinib; AND	Compliance with Authority Required procedures - Streamlined Authority Code 16264

			Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer; AND Patient must have a WHO performance status of 0 or 1; AND The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material; AND The treatment must not exceed a total of 4 doses under this restriction.	
C16280	P16280	Pembrolizumab	Stage IV (metastatic) non-small cell lung cancer (NSCLC) Initial treatment - 3 weekly treatment regimen Patient must not have previously been treated for this condition in the metastatic setting; OR The condition must have progressed after treatment with only one of (i) tepotinib, (ii) selpercatinib; AND Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer; AND Patient must have a WHO performance status of 0 or 1; AND The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material; AND The treatment must not exceed a total of 7 doses under this restriction.	Compliance with Authority Required procedures - Streamlined Authority Code 16280