PB 116 of 2024

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

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*.

Dated 30 October 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 (November Update) Instrument 2024*

(2) This instrument may also be cited as PB 116 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 November 2024*	*1 November 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Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 2024 (PB 31 of 2024)

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

(a) *omit from the column headed "Circumstances":* **C8947 C10023**

(b) *insert in numerical order in the column headed "Circumstances":* **C16053 C16085**

[2] Schedule 1, Part 2, entry for Avelumab *[Maximum Amount: 1200 mg; Number of Repeats: 8]*

omit from the column headed "Purposes": **P8947** *substitute:* **P16053**

[3] Schedule 1, Part 2, entry for Avelumab *[Maximum Amount: 1200 mg; Number of Repeats: 11]*

omit from the column headed "Purposes": **P10023** *substitute:* **P16085**

[4] Schedule 3, Part 1, omit entry for Circumstances Code "C8947"

[5] Schedule 3, Part 1, omit entry for Circumstances Code "C10023"

[6] Schedule 3, Part 1, after entry for Circumstances Code "C15832"

insert:

C16053	P16053	Avelumab	Stage IV (metastatic) Merkel Cell Carcinoma Initial treatment The treatment must be the sole PBS-subsidised therapy for this condition; AND The treatment must not exceed a total of 9 doses at a maximum dose of 10 mg per kg every 2 weeks under this restriction; OR The treatment must not exceed a dose of 800 mg every 2 weeks under this restriction. 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 16053
C16085	P16085	Avelumab	Stage IV (metastatic) Merkel Cell Carcinoma 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 have developed disease progression while being treated with this drug for this	Compliance with Authority Required procedures - Streamlined Authority Code 16085

	condition; AND The treatment must not exceed a maximum dose of 10 mg per kg every 2 weeks under this restriction; OR The treatment must not exceed a dose of 800 mg every 2 weeks under this restriction.