

**PB 89 of 2025**

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

*National Health Act 1953*

I, REBECCA RICHARDSON, Assistant Secretary, PBS Listing, Pricing and 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 28 July 2025

**REBECCA RICHARDSON**

Assistant Secretary

PBS Listing, Pricing and Policy Branch

Technology Assessment and Access Division

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1. Name
2. This instrument is the *National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment (August Update) Instrument 2025.*
3. This instrument may also be cited as PB 89 of 2025.
4. Commencement
5. 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 August 2025 | 1 August 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Note: This table relates only to the provisions of this instrument as originally made.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.

1. 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.
2. Authority

This instrument is made under subsection 100(2) of the *National Health Act 1953*.

1. 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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 Arsenic**

*omit:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  | Arsenic Trioxide‑AFT | C4793 C5997 C6018 |

1. **Schedule 1, Part 1, entry for Bortezomib in the form Powder for injection 3.5 mg**

*omit:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  | Bortezomib Sandoz | C11099 C13745 |

1. **Schedule 1, Part 1, entry for Durvalumab in each of the forms: Solution concentrate for I.V. infusion 120 mg in 2.4 mL; and Solution concentrate for I.V. infusion 500 mg in 10 mL**

*insert in numerical order in the column headed “Circumstances”:* **C16814 C16953**

1. **Schedule 1, Part 1, entry for Fluorouracil in the form Injection 1000 mg in 20 mL**

*omit:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  | Fluorouracil Ebewe | C6266 C6297 |

1. **Schedule 1, Part 1, entry for Fluorouracil in the form Injection 5000 mg in 100 mL**

*omit:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  | Fluorouracil Ebewe | C6266 C6297 |

1. **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**
   1. *omit from the column headed “Circumstances”:* **C14808**
   2. *insert in numerical order in the column headed “Circumstances”:* **C16936**
2. **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**
3. *omit from the column headed “Circumstances”:* **C10119 C10120**
4. *omit from the column headed “Circumstances”:* **C14816**
5. *insert in numerical order in the column headed “Circumstances”:* **C16935 C16961 C16962**
6. **Schedule 1, Part 1, entry for Nivolumab with relatlimab**
   1. *omit from the column headed “Circumstances”:* **C16188**
   2. *insert in numerical order in the column headed “Circumstances”:* **C16881**
7. **Schedule 1, Part 1, entry for Pembrolizumab**
   1. *omit from the column headed “Circumstances”:* **C14817 C14818**
   2. *insert in numerical order in the column headed “Circumstances”:* **C16933 C16950**
8. **Schedule 1, Part 2, entry for Durvalumab**

*insert as first entry:*

|  |  |  |  |
| --- | --- | --- | --- |
|  | P16953 | 1120 mg | 5 |

1. **Schedule 1, Part 2, entry for Durvalumab *[Maximum Amount: 1500 mg; Number of Repeats: 5]***

*insert in numerical order in the column headed “Purposes”:* **P16814**

1. **Schedule 1, Part 2, entry for Ipilimumab *[Maximum Amount: 360 mg; Number of Repeats: 3]***
   1. *omit from the column headed “Purposes”:* **P14808**
   2. *insert in numerical order in the column headed “Purposes”:* **P16936**
2. **Schedule 1, Part 2, entry for Nivolumab *[Maximum Amount: 480 mg; Number of Repeats: 5]***
   1. *omit from the column headed “Purposes”:* **P10119 P10120**
   2. *insert in numerical order in the column headed “Purposes”:* **P16935 P16962**
3. **Schedule 1, Part 2, entry for Nivolumab *[Maximum Amount: 480 mg; Number of Repeats: 8]***
   1. *omit from the column headed “Purposes”:* **P14816**
   2. *insert in numerical order in the column headed “Purposes”:* **P16961**
4. **Schedule 1, Part 2, entry for Nivolumab with relatlimab *[Maximum Amount: 480 mg; Number of Repeats: 8]***

*omit from the column headed “Purposes”:* **P16188** *substitute:* **P16881**

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

*omit from the column headed “Purposes”:* **P14818** *substitute:* **P16950**

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

*omit from the column headed “Purposes”:* **P14817** *substitute:* **P16933**

1. **Schedule 2, entry for Granisetron in the form Concentrated injection 3 mg (as hydrochloride) in 3 mL**

*omit:*

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Granisetron‑AFT | C4139 |  | 1 | 0 | V4139 |

1. **Schedule 3, Part 1, omit entry for Circumstances Code “C10119”**
2. **Schedule 3, Part 1, omit entry for Circumstances Code “C10120”**
3. **Schedule 3, Part 1, omit entry for Circumstances Code “C14808”**
4. **Schedule 3, Part 1, omit entry for Circumstances Code “C14816”**
5. **Schedule 3, Part 1, omit entry for Circumstances Code “C14817”**
6. **Schedule 3, Part 1, omit entry for Circumstances Code “C14818”**
7. **Schedule 3, Part 1, omit entry for Circumstances Code “C16188”**
8. **Schedule 3, Part 1, after entry for Circumstances Code “C16790”**

*insert:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| C16814 | P16814 | Durvalumab | Advanced, metastatic or recurrent endometrial carcinoma  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.  Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 36 cumulative months from the first administered dose, once in a lifetime.  Retain all pathology imaging and investigative test results in the patient's medical records.  Patients with a body weight of 30 kg or less during continuing treatment must receive weight-based dosing, equivalent to durvalumab 20 mg/kg, until weight is greater than 30 kg. | Compliance with Authority Required procedures - Streamlined Authority Code 16814 |
| C16881 | P16881 | Nivolumab with relatlimab | 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 either: (i) PD-1 inhibitor treatment, (ii) CTLA-4 inhibitor treatment, if previously treated for resected or resectable melanoma; OR  Patient must not have experienced disease recurrence within 6 months of completing either: (i) PD-1 inhibitor treatment, (ii) CTLA-4 inhibitor treatment, if previously treated for resected or resectable melanoma; AND  Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; AND  The condition must not be uveal melanoma; AND  The treatment must be the sole PBS-subsidised therapy for this condition.  Patient must weigh 40 kg or more; AND  Patient must be at least 12 years of age.  Patients must only receive a maximum of 480 mg nivolumab and 160 mg relatlimab every four weeks under a flat dosing regimen.  The prescribed dose must be according to the Therapeutic Goods Administration (TGA) Product Information.  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. | Compliance with Authority Required procedures - Streamlined Authority Code 16881 |
| C16933 | P16933 | Pembrolizumab | 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 either: (i) PD-1 inhibitor treatment, (ii) CTLA-4 inhibitor treatment, if previously treated for resected or resectable melanoma; OR  Patient must not have experienced disease recurrence within 6 months of completing either: (i) PD-1 inhibitor treatment, (ii) CTLA-4 inhibitor treatment, if previously treated for resected or resectable 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 16933 |
| C16935 | P16935 | Nivolumab | Stage IIIB, IIIC, IIID or Stage IV malignant melanoma  Initial treatment  The treatment must be in addition to complete surgical resection; AND  Patient must have a WHO performance status of 1 or less; AND  Patient must not have received prior PBS-subsidised treatment for this condition; AND  The treatment must commence within 12 weeks of complete resection; AND  Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.  When nivolumab is initially prescribed as a 3-weekly dosing regimen, patients must only receive a maximum of 240 mg every 3 weeks for 2 cycles (i.e., 1 repeat). When prescribed as a weight based or flat dose adjuvant regimen, patients must only receive a maximum of 240 mg every 2 weeks or 480 mg every 4 weeks for a maximum of 12 months of adjuvant treatment. | Compliance with Authority Required procedures |
| C16936 | P16936 | Ipilimumab | 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.  Prescribed amounts must be consistent with the treatment protocol used for an individual patient.  Prescribers may apply through this restriction for patients initiated on 80 mg every 3 weeks for 2 cycles (i.e., 1 repeat). Prescribers may also apply through this restriction when the condition progresses to unresectable/metastatic melanoma at the recommended dosing regimen.  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 16936 |
| C16950 | P16950 | Pembrolizumab | 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 either: (i) PD-1 inhibitor treatment, (ii) CTLA-4 inhibitor treatment, if previously treated for resected or resectable melanoma; OR  Patient must not have experienced disease recurrence within 6 months of completing either: (i) PD-1 inhibitor treatment, (ii) CTLA-4 inhibitor treatment, if previously treated for resected or resectable 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 16950 |
| C16953 | P16953 | Durvalumab | Advanced, metastatic or recurrent endometrial carcinoma  Initial treatment covering the first 6 treatment cycles  Patient must have deficient mismatch repair (dMMR) endometrial cancer, as determined by immunohistochemistry test; AND  The condition must be unsuitable for at least one of the following: (i) curative surgical resection, (ii) curative radiotherapy; AND  The treatment must be initiated in combination with platinum-containing chemotherapy; AND  The condition must be, at treatment initiation with this drug, either: (i) untreated with systemic therapy, (ii) treated with neoadjuvant/adjuvant systemic therapy, but the cancer has recurred or progressed after more than 6 months from the last dose of systemic therapy; 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 this condition; AND  Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation.  Retain all pathology imaging and investigative test results in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 16953 |
| C16961 | P16961 | Nivolumab | 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  Patient must not have experienced disease progression whilst on either: (i) PD-1 inhibitor treatment, (ii) CTLA-4 inhibitor treatment, if previously treated for resected or resectable melanoma; OR  Patient must not have experienced disease recurrence within 6 months of completing either: (i) PD-1 inhibitor treatment, (ii) CTLA-4 inhibitor treatment, if previously treated for resected or resectable 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 16961 |
| C16962 | P16962 | Nivolumab | Stage IIIB, IIIC, IIID or Stage IV malignant melanoma  Continuing treatment  Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND  Patient must have undergone surgical resection; AND  Patient must not have experienced disease recurrence; AND  The treatment must be the sole PBS-subsidised therapy for this condition; AND  Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.  When prescribed as a weight based or flat dose adjuvant regimen, patients must receive a maximum of 240 mg every 2 weeks or 480 mg every 4 weeks for a maximum of 12 months of adjuvant treatment. | Compliance with Authority Required procedures |