

**PB 6 of 2024**

**National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2024 (No. 1)**

*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*.

Date 31 January 2024

**NIKOLAI TSYGANOV**

Assistant Secretary

Pricing and PBS 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 Instrument 2024 (No. 1)*
3. This instrument may also be cited as PB 6 of 2024.
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 February 2024* | *1 February 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Note: This table relates only to the provisions of this instrument as originally made.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.

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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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 2011 (PB 79 of 2011)*

1. **Schedule 1, Part 1, entry for Bleomycin**

*omit:*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | CIPLA BLEOMYCIN | LR | MP | C6224 C6275 | D |

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**
2. *omit from the column headed “Circumstances”:* **C13841**
3. *insert in numerical order in the column headed “Circumstances”:* **C14808**
4. **Schedule 1, Part 1, entry for Irinotecan in each of the forms:** **I.V. injection containing irinotecan hydrochloride trihydrate 40 mg in 2 mL; and I.V. injection containing irinotecan hydrochloride trihydrate 100 mg in 5 mL**

*omit:*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | MEDITAB IRINOTECAN | LR | MP |  | D |

1. **Schedule 1, Part 1, entry for Methotrexate in the form** **Solution concentrate for I.V. infusion 1000 mg in 10 mL vial**

*omit:*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Pfizer Australia Pty Ltd | PF | MP |  | PB |

1. **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**
2. *omit from the column headed “Circumstances”:* **C10155**
3. *omit from the column headed “Circumstances”:* **C13853**
4. *insert in numerical order in the column headed “Circumstances”:* **C14816 C14830**
5. **Schedule 1, Part 1, entry for Pembrolizumab**
6. *omit from the column headed “Circumstances”:* **C10689 C10696**
7. *insert in numerical order in the column headed “Circumstances”:* **C14817 C14818**
8. **Schedule 1, Part 1, after entry for Sacituzumab govitecan**

*insert:*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Tebentafusp | Solution concentrate for I.V. infusion 100 micrograms in 0.5 mL | Injection | Kimmtrak | WM | MP | C14813 C14821 C14822 C14825 | D |

1. **Schedule 1, Part 2, entry for Ipilimumab *[Maximum Amount: 360 mg; Number of Repeats: 3]***
2. *omit from the column headed “Purposes”:* **P13841**
3. *insert in numerical order in the column headed “Purposes”:* **P14808**
4. **Schedule 1, Part 2, entry for Nivolumab *[Maximum Amount: 120 mg; Number of Repeats: 3]***
5. *omit from the column headed “Purposes”:* **P13853**
6. *insert in numerical order in the column headed “Purposes”:* **P14830**
7. **Schedule 1, Part 2, entry for Nivolumab *[Maximum Amount: 480 mg; Number of Repeats: 8]***
8. *omit from the column headed “Purposes”:* **P10155**
9. *insert in numerical order in the column headed “Purposes”:* **P14816**
10. **Schedule 1, Part 2, entry for Pembrolizumab *[Maximum Amount: 200 mg; Number of Repeats: 5]***

*omit from the column headed “Purposes”:* **P10696** *substitute:* **P14818**

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

*omit from the column headed “Purposes”:* **P10689** *substitute:* **P14817**

1. **Schedule 1, Part 2, after entry for Sacituzumab govitecan *[Maximum Amount: 1200 mg; Number of Repeats: 13]***

*insert:*

|  |  |  |  |
| --- | --- | --- | --- |
| Tebentafusp | P14813 | 20 mcg | 0 |
|  | P14821 | 30 mcg | 0 |
|  | P14825 | 68 mcg | 0 |
|  | P14822 | 136 mcg | 7 |

1. **Schedule 2, entry for Ondansetron in the form Tablet (orally disintegrating) 4 mg**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Ondansetron AN ODT | EA | MP | C5743 |  | 4 | 0 | C |

1. **Schedule 2, entry for Ondansetron in the form Tablet 4 mg (as hydrochloride dihydrate)**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Ondansetron AN | EA | MP | C5778 |  | 4 | 0 | C |

1. **Schedule 2, entry for Ondansetron in the form Tablet (orally disintegrating) 8 mg**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Ondansetron AN ODT | EA | MP | C5743 |  | 4 | 0 | C |

1. **Schedule 2, entry for Ondansetron in the form Tablet 8 mg (as hydrochloride dihydrate)**

*omit:*

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Ondansetron AN | EA | MP | C5778 |  | 4 | 0 | C |

1. **Schedule 2, entry for Palonosetron**

*insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:*

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | PALONOSETRON Medsurge | DZ | MP | C5805 |  | 1 | 0 | C |

1. **Schedule 3, after details relevant to Responsible Person code CR**

*insert:*

|  |  |  |
| --- | --- | --- |
| DZ | Medsurge Healthcare Pty Ltd | 92 124 728 892 |

1. **Schedule 3**

*omit:*

|  |  |  |
| --- | --- | --- |
| EA | Amneal Pharmaceuticals Pty Ltd | 11 163 167 851  |

1. **Schedule 3, after details relevant to Responsible Person code TY**

*insert:*

|  |  |  |
| --- | --- | --- |
| WM | MEDISON PHARMA AUSTRALIA PTY LIMITED | 19 659 723 403 |

1. **Schedule 4, entry for Ipilimumab**
2. *omit:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | C13841 | P13841 | Unresectable Stage III or Stage IV malignant melanomaInduction treatmentPatient 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; ANDPatient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; ANDThe condition must not be ocular or uveal melanoma; ANDThe treatment must be in combination with PBS‑subsidised treatment with nivolumab as induction therapy for this condition.Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks.Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.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 13841 |

1. *insert in numerical order after existing text:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | C14808 | P14808 | Unresectable Stage III or Stage IV malignant melanomaInduction treatmentPatient 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; ANDPatient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; ANDThe condition must not be ocular or uveal melanoma; ANDThe treatment must be in combination with PBS-subsidised treatment with nivolumab as induction therapy for this condition.Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks.Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.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 14808 |

1. **Schedule 4, entry for Nivolumab**
2. *omit:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | C10155 | P10155 | Unresectable Stage III or Stage IV malignant melanomaInitial treatmentPatient 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; ANDPatient 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; ANDThe 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 10155 |

1. *omit:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | C13853 | P13853 | Unresectable Stage III or Stage IV malignant melanomaInduction treatmentPatient 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; ANDPatient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; ANDThe condition must not be ocular or uveal melanoma; ANDThe treatment must be in combination with PBS‑subsidised treatment with ipilimumab as induction for this condition.Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks.Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks. | Compliance with Authority Required procedures ‑ Streamlined Authority Code 13853 |

1. *insert in numerical order after existing text:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | C14816 | P14816 | Unresectable Stage III or Stage IV malignant melanomaInitial treatmentPatient 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; ANDPatient 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; ANDThe 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 14816 |
|  | C14830 | P14830 | Unresectable Stage III or Stage IV malignant melanomaInduction treatmentPatient 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; ANDPatient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; ANDThe condition must not be ocular or uveal melanoma; ANDThe treatment must be in combination with PBS-subsidised treatment with ipilimumab as induction for this condition.Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks.Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks. | Compliance with Authority Required procedures - Streamlined Authority Code 14830 |

1. **Schedule 4, entry for Pembrolizumab**
2. *omit:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | C10689 | P10689 | Unresectable Stage III or Stage IV malignant melanomaInitial treatment ‑ 6 weekly treatment regimenPatient 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; ANDPatient 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; ANDThe treatment must be the sole PBS‑subsidised therapy for this condition; ANDThe treatment must not exceed a total of 3 doses under this restriction. | Compliance with Authority Required procedures ‑ Streamlined Authority Code 10689 |
|  | C10696 | P10696 | Unresectable Stage III or Stage IV malignant melanomaInitial treatment ‑ 3 weekly treatment regimenPatient 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; ANDPatient 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; ANDThe treatment must be the sole PBS‑subsidised therapy for this condition; ANDThe treatment must not exceed a total of 6 doses under this restriction. | Compliance with Authority Required procedures ‑ Streamlined Authority Code 10696 |

1. *insert in numerical order after existing text:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | C14817 | P14817 | Unresectable Stage III or Stage IV malignant melanomaInitial treatment - 6 weekly treatment regimenPatient 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; ANDPatient 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; ANDThe treatment must be the sole PBS-subsidised therapy for this condition; ANDThe treatment must not exceed a total of 3 doses under this restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 14817 |
|  | C14818 | P14818 | Unresectable Stage III or Stage IV malignant melanomaInitial treatment - 3 weekly treatment regimenPatient 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; ANDPatient 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; ANDThe treatment must be the sole PBS-subsidised therapy for this condition; ANDThe treatment must not exceed a total of 6 doses under this restriction. | Compliance with Authority Required procedures - Streamlined Authority Code 14818 |

1. **Schedule 4, after entry for Sacituzumab govitecan**

*insert:*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Tebentafusp | C14813 | P14813 | Advanced (unresectable or metastatic) uveal melanomaInitial treatment - day 1Patient must have HLA-A\*02:01-positive disease; ANDPatient must have uveal melanoma that has been confirmed either (i) histologically, (ii) cytologically; ANDThe treatment must be the sole PBS-subsidised therapy for this condition; ANDPatient must not have received prior systemic therapy for metastatic disease.Patient must be at least 18 years of age.According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 doses (on Days 1, 8 and 15) and for at least 16 hours after each infusion is completed. If the patient does not experience hypotension that is Grade 2 or worse (requiring medical intervention) with the third dose, subsequent doses can be administered in an appropriate outpatient/ambulatory care setting. Supervision by a health care professional is recommended for a minimum of 30 minutes following each infusion.This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.Positive HLA-A\*02:01 assessment must be documented in the patient's medical records. | Compliance with Authority Required procedures |
|  | C14821 | P14821 | Advanced (unresectable or metastatic) uveal melanomaInitial treatment - day 8Patient must have HLA-A\*02:01-positive disease; ANDPatient must have previously received PBS-subsidised initial day 1 treatment with this drug for this condition; ANDThe treatment must be the sole PBS-subsidised therapy for this condition.According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 doses (on Days 1, 8 and 15) and for at least 16 hours after each infusion is completed. If the patient does not experience hypotension that is Grade 2 or worse (requiring medical intervention) with the third dose, subsequent doses can be administered in an appropriate outpatient/ambulatory care setting. Supervision by a health care professional is recommended for a minimum of 30 minutes following each infusion.This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.Positive HLA-A\*02:01 assessment must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 14821 |
|  | C14822 | P14822 | Advanced (unresectable or metastatic) uveal melanomaContinuing treatmentThe treatment must be the sole PBS-subsidised therapy for this condition; ANDPatient must have previously received PBS-subsidised treatment with this drug for this condition; ANDPatient must not receive PBS-subsidised treatment with this drug for this condition if it is no longer determined to be clinically beneficial by the treating clinician.According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 doses (on Days 1, 8 and 15) and for at least 16 hours after each infusion is completed. If the patient does not experience hypotension that is Grade 2 or worse (requiring medical intervention) with the third dose, subsequent doses can be administered in an appropriate outpatient/ambulatory care setting. Supervision by a health care professional is recommended for a minimum of 30 minutes following each infusion. | Compliance with Authority Required procedures - Streamlined Authority Code 14822 |
|  | C14825 | P14825 | Advanced (unresectable or metastatic) uveal melanomaInitial treatment - day 15Patient must have HLA-A\*02:01-positive disease; ANDPatient must have previously received PBS-subsidised initial day 8 treatment with this drug for this condition; ANDThe treatment must be the sole PBS-subsidised therapy for this condition.According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 doses (on Days 1, 8 and 15) and for at least 16 hours after each infusion is completed. If the patient does not experience hypotension that is Grade 2 or worse (requiring medical intervention) with the third dose, subsequent doses can be administered in an appropriate outpatient/ambulatory care setting. Supervision by a health care professional is recommended for a minimum of 30 minutes following each infusion.This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.Positive HLA-A\*02:01 assessment must be documented in the patient's medical records. | Compliance with Authority Required procedures - Streamlined Authority Code 14825 |