**PB 108 of 2023**

# National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment Instrument 2023 (No. 10)

*National Health Act 1953*

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I, EDEN SIMON, Assistant Secretary (Acting), 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 30 October 2023

**EDEN SIMON**
Assistant Secretary (Acting)
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 Instrument 2023 (No. 10)*

(2) This instrument may also be cited as PB 108 of 2023.

## 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 2023* | *1 November 2023* |

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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

**[1] Schedule 1, Part 1, entry for Blinatumomab**

**(a)** *omit from the column headed "Circumstances":* **C9911 C9936 C9937**

**(b)** *insert in numerical order in the column headed "Circumstances":* **C14587 C14588 C14631**

**[2] Schedule 1, Part 1, entry for Bortezomib in the form Powder for injection 1 mg**

*omit:*

| | | | | | | |
|---|---|---|---|---|---|---|
| | | Bortezomib Juno | JU | MP | C11099 C13745 | D |

**[3] Schedule 1, Part 1, entry for Irinotecan in the form I.V. injection containing irinotecan hydrochloride trihydrate 100 mg in 5 mL**

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

| | | | | | | |
|---|---|---|---|---|---|---|
| | | IRINOTECAN BAXTER | BX | MP | | D |

**[4] Schedule 1, Part 1, after entry for Trastuzumab in the form Powder for I.V. infusion 440 mg with diluent**

*insert:*

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Trastuzumab deruxtecan | Powder for I.V. infusion 100 mg | Injection | Enhertu | AP | MP | C14470 | D |

**[5] Schedule 1, Part 2**

*omit table and substitute:*

| Listed Drug | Purposes | Maximum Amount | Number of Repeats |
|---|---|---|---|
| Arsenic | P4793 P5997 | 18 mg | 89 |
| | P6018 | 18 mg | 140 |
| Atezolizumab | P10206 P10939 | 1200 mg | 3 |
| | P10521 | 1200 mg | 4 |

| | | | |
|---|---|---|---|
| | P10125 P13443 P13448 | 1200 mg | 5 |
| | P10216 P10297 P13442 | 1200 mg | 7 |
| | P10917 | 1200 mg | 8 |
| | P10509 P13446 | 1680 mg | 3 |
| | P10215 P10257 P10972 P13451 | 1680 mg | 5 |
| Avelumab | P13303 P13313 | 800 mg | 7 |
| | P13290 | 800 mg | 11 |
| | P8947 | 1200 mg | 8 |
| | P10023 | 1200 mg | 11 |
| Bendamustine | | 200 mg | 11 |
| Bevacizumab | | 1800 mg | 7 |
| Bleomycin | | 30000 iu | 11 |
| Blinatumomab | P14588 | 651 mcg | 0 |
| | P9519 | 784 mcg | 0 |
| | P14587 P14631 | 784 mcg | 1 |
| | P9369 | 784 mcg | 2 |
| Bortezomib | | 3000 mcg | 15 |
| Brentuximab vedotin | P13179 | 180 mg | 3 |
| | P13181 | 180 mg | 11 |
| | P13212 | 200 mg | 1 |
| | P13182 P13209 P13259 | 200 mg | 3 |
| | P13134 | 200 mg | 5 |
| | P13208 P13231 P13261 | 200 mg | 11 |

| | | | |
|---|---|---|---|
| Cabazitaxel | | 55 mg | 5 |
| Carboplatin | | 900 mg | 5 |
| Carfilzomib | P14363 P14364 P14389 | 60 mg | 17 |
| | P12930 P12934 | 120 mg | 17 |
| | P12694 P12849 | 160 mg | 8 |
| Cemiplimab | P13419 | 350 mg | 2 |
| | P13373 P13766 | 350 mg | 6 |
| | P13322 P13411 | 350 mg | 7 |
| Cetuximab | P4788 | 550 mg | 5 |
| | P12016 P12470 | 550 mg | 11 |
| | P4912 | 550 mg | 18 |
| | P4785 P4794 P4908 P12045 P12483 | 880 mg | 0 |
| Cisplatin | | 220 mg | 14 |
| Cladribine | | 17 mg | 6 |
| Cyclophosphamide | | 2800 mg | 17 |
| Cytarabine | | 7000 mg | 15 |
| Daratumumab | P12845 | 1920 mg | 4 |
| | P12691 | 1920 mg | 5 |
| | P12844 | 1920 mg | 7 |
| | P13752 | 1920 mg | 8 |
| Docetaxel | | 250 mg | 5 |
| Doxorubicin | | 135 mg | 11 |

| | | | |
|---|---|---|---|
| Doxorubicin - pegylated liposomal | | 100 mg | 5 |
| Durvalumab | | 1500 mg | 4 |
| Elotuzumab | P12847 | 1200 mg | 5 |
| | P12891 | 1200 mg | 9 |
| Enfortumab vedotin | | 125 mg | 8 |
| Epirubicin | | 220 mg | 5 |
| Eribulin | P7258 P7280 | 3 mg | 7 |
| | P4649 | 3 mg | 13 |
| Etoposide | | 440 mg | 14 |
| Fludarabine | | 55 mg | 29 |
| Fluorouracil | P6297 | 1000 mg | 23 |
| | P6266 | 5500 mg | 11 |
| Gemcitabine | | 3000 mg | 17 |
| Gemtuzumab ozogamicin | P12566 | 5 mg | 1 |
| | P12559 | 5 mg | 2 |
| Idarubicin | | 30 mg | 5 |
| Ifosfamide | | 4000 mg | 19 |
| Inotuzumab ozogamicin | P9601 | 2820 mcg | 4 |
| | P9470 | 3384 mcg | 2 |
| Ipilimumab | P8555 P11930 | 120 mg | 3 |
| | P11391 P11478 | 120 mg | 4 |
| | P6562 P6585 P13841 | 360 mg | 3 |
| Irinotecan | | 800 mg | 11 |

| | | | |
|---|---|---|---|
| Methotrexate | | 250 mg | 5 |
| | P6276 | 20000 mg | 0 |
| Mitozantrone | | 30 mg | 5 |
| Nivolumab | P13852 P13853 | 120 mg | 3 |
| | P14001 | 360 mg | 3 |
| | P11985 | 360 mg | 8 |
| | P11468 P13433 | 360 mg | 13 |
| | P10119 P10120 P13900 | 480 mg | 5 |
| | P9216 P9312 P10155 P13445 | 480 mg | 8 |
| | P9252 P9298 P9299 P9321 P11477 P13839 P13863 | 480 mg | 11 |
| | P13888 | 480 mg | 13 |
| Obinutuzumab | P11785 P11787 | 1000 mg | 5 |
| | P11755 P14326 | 1000 mg | 7 |
| | P11015 | 1000 mg | 8 |
| | P11815 | 1000 mg | 9 |
| Oxaliplatin | | 300 mg | 11 |
| Paclitaxel | | 450 mg | 3 |
| Paclitaxel, nanoparticle albumin-bound | P4657 | 275 mg | 11 |
| | P6106 P6119 | 580 mg | 5 |
| Panitumumab | P12035 P12066 | 720 mg | 5 |
| | P5452 P5526 | 720 mg | 9 |
| Pembrolizumab | P10696 | 200 mg | 5 |

| | | | |
|---|---|---|---|
| | P13431 P13432 | 200 mg | 6 |
| | P10687 P10695 P10705 | 200 mg | 7 |
| | P10689 | 400 mg | 2 |
| | P10676 P10688 P10701 P13436 P13437 | 400 mg | 3 |
| | P13726 P13727 P13728 P13730 P13731 P13732 P13735 P13736 P13738 P13739 P13741 P13948 P13949 P13986 P14027 P14028 P14044 P14324 P14403 P14404 P14405 | 400 mg | 6 |
| Pemetrexed | | 1100 mg | 5 |
| Pertuzumab | P10414 | 420 mg | 3 |
| | P13018 | 840 mg | 0 |
| Pralatrexate | P7558 | 80 mg | 5 |
| | P7526 | 80 mg | 11 |
| Raltitrexed | | 7 mg | 8 |
| Rituximab | | 800 mg | 11 |
| Sacituzumab govitecan | P12656 | 1200 mg | 7 |
| | P12669 | 1200 mg | 13 |
| Topotecan | | 3500 mcg | 17 |
| Trabectedin | P14196 | 3250 mcg | 3 |
| | P14188 P14197 | 3250 mcg | 7 |
| Trastuzumab | P10213 | 250 mg | 9 |
| | P10296 | 500 mg | 0 |
| | P9349 P9571 P10294 | 750 mg | 3 |

| | | | |
|---|---|---|---|
| | P9353 P9573 P10293 | 1000 mg | 0 |
| Trastuzumab deruxtecan | | 675 mg | 8 |
| Trastuzumab emtansine | P10295 P13004 | 450 mg | 6 |
| | P12989 P13017 | 450 mg | 8 |
| Vinblastine | | 20 mg | 17 |
| Vincristine | | 2 mg | 7 |
| Vinorelbine | | 70 mg | 7 |

**[6] Schedule 2, entry for Fosaprepitant**

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

| | | | | | | |
|---|---|---|---|---|---|---|
| FOSAPREPITANT MSN | RQ | MP | C6852 C6886 C6887 C6891 | 1 | 5 | |

**[7] Schedule 4, entry for Blinatumomab**

**(a)** *omit:*

| | | | | |
|---|---|---|---|---|
| | C9911 | P9911 | Acute lymphoblastic leukaemia<br>Induction treatment<br>The condition must be relapsed or refractory B-precursor cell ALL, with an Eastern Cooperative Oncology Group (ECOG) performance status of 2 or less; AND<br>The condition must not be present in the central nervous system or testis; AND<br>Patient must have previously received a tyrosine kinase inhibitor (TKI) if the condition is Philadelphia chromosome positive; AND<br>Patient must have received intensive combination chemotherapy for initial treatment of ALL or for subsequent salvage therapy; AND<br>Patient must not have received more than 1 line of salvage therapy; AND<br>Patient must not have received blinatumomab previously for the treatment of minimal residual disease; OR<br>Patient must have had a relapse-free period of at least six months following completion of treatment with blinatumomab for minimal residual disease; AND<br>The condition must have more than 5% blasts in bone marrow; AND<br>The treatment must not be more than 2 treatment cycles under this restriction in a lifetime.<br>According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 9 days of the first cycle and the first 2 days of the second cycle. For all subsequent cycle starts and re-initiation (e.g. if treatment is interrupted for 4 or more hours), supervision by a | Compliance with Written Authority Required procedures |

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| | | | health care professional or hospitalisation is recommended.<br>An amount of 651 microgram will be sufficient for a continuous infusion of blinatumomab over 28 days in cycle 1. An amount of 784 microgram, which may be obtained under Induction treatment - balance of supply restriction, will be sufficient for a continuous infusion of blinatumomab over 28 days in cycle 2.<br>Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.<br>The authority application must be made in writing and must include:<br>(1) a completed authority prescription form; and<br>(2) a completed Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and<br>(3) date of most recent chemotherapy, and if this was the initial chemotherapy regimen or salvage therapy, including what line of salvage; and<br>(4) if applicable, the date of completion of blinatumomab treatment for minimal residual disease and the date of the patient's subsequent relapse; and<br>(5) the percentage blasts in bone marrow count that is no more than 4 weeks old at the time of application. | |
| | C9936 | P9936 | Minimal residual disease of precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL)<br>Continuing treatment of previously detectable minimal residual disease of Pre-B-cell ALL<br>Must be treated by a physician experienced in the treatment of haematological malignancies.<br>Patient must have previously received PBS-subsidised initial treatment with this drug for this condition; AND<br>Patient must have achieved a complete remission; AND<br>Patient must be minimal residual disease negative, defined as either undetectable using the same method used to determine original eligibility or less than $10^{-4}$(0.01%) blasts based on measurement in bone marrow; AND<br>Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition; AND<br>The treatment must not be more than 2 treatment cycles under this restriction in a lifetime.<br>For all subsequent cycle starts and re-initiation (e.g. if treatment is interrupted for four or more hours), supervision by a health care professional or hospitalisation is recommended.<br>An amount of 784 microgram will be sufficient for a continuous infusion of blinatumomab over 28 days in each cycle.<br>Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.<br>Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent. | Compliance with Authority Required procedures |
| | C9937 | P9937 | Minimal residual disease of precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL)<br>Initial treatment of minimal residual disease of Pre-B-cell ALL<br>Must be treated by a physician experienced in the treatment of haematological malignancies.<br>Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; AND<br>The condition must not be present in the central nervous system or testis; AND | Compliance with Written Authority Required procedures |

| | | | | |
|---|---|---|---|---|
| | | | Patient must have achieved complete remission following intensive combination chemotherapy for initial treatment of acute lymphoblastic leukaemia (ALL) or for subsequent salvage therapy; AND<br>Patient must have minimal residual disease defined as at least $10^{-4}$(0.01%) blasts based on measurement in bone marrow, documented after an interval of at least 2 weeks from the last course of systemic chemotherapy given as intensive combination chemotherapy treatment of ALL or as subsequent salvage therapy, whichever was the later, and measured using polymerase chain reaction or flow cytometry; AND<br>The treatment must not be more than 2 treatment cycles under this restriction in a lifetime.<br>According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 days of the first cycle and the first 2 days of the second cycle.<br>For all subsequent cycle starts and re-initiation (e.g. if treatment is interrupted for four or more hours), supervision by a health care professional or hospitalisation is recommended.<br>An amount of 784 mcg will be sufficient for a continuous infusion of blinatumomab over 28 days in each cycle.<br>Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.<br>The authority application must be made in writing and must include:<br>(1) a completed authority prescription form; and<br>(2) a completed Minimal residual disease positive Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and<br>(3) date of most recent chemotherapy, and if this was the initial chemotherapy regimen or salvage therapy; and<br>(4) the percentage blasts in bone marrow count that is no more than 4 weeks old at the time of application<br>Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent. | |

**(b)** *insert in numerical order after existing text:*

| | | | | |
|---|---|---|---|---|
| | C14587 | P14587 | Measurable residual disease of precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL)<br>Continuing treatment of previously measurable residual disease of Pre-B-cell ALL<br>Must be treated by a physician experienced in the treatment of haematological malignancies.<br>Patient must have previously received PBS-subsidised initial treatment with this drug for this condition; AND<br>Patient must have achieved a complete remission; AND<br>The condition must be negative for measurable residual disease using the same method used to determine initial PBS eligibility; AND<br>Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND<br>The treatment must not be more than 2 treatment cycles under this restriction in a lifetime.<br>For all subsequent cycle starts and re-initiation (e.g. if treatment is interrupted for four or more hours), supervision by a health care professional or hospitalisation is recommended.<br>An amount of 784 microgram will be sufficient for a continuous infusion of blinatumomab over 28 days in each cycle.<br>Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital | Compliance with Authority Required procedures |

| | | | |
|---|---|---|---|
| | | setting.<br>Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent. | |
| C14588 | P14588 | Acute lymphoblastic leukaemia<br>Induction treatment<br>The condition must be relapsed or refractory B-precursor cell ALL, with an Eastern Cooperative Oncology Group (ECOG) performance status of 2 or less; AND<br>The condition must not be present in the central nervous system or testis; AND<br>Patient must have previously received a tyrosine kinase inhibitor (TKI) if the condition is Philadelphia chromosome positive; AND<br>Patient must have received intensive combination chemotherapy for initial treatment of ALL or for subsequent salvage therapy; AND<br>Patient must not have received more than 1 line of salvage therapy; AND<br>The condition must be one of the following: (i) untreated with this drug for measurable residual disease, (ii) treated with this drug for measurable residual disease, but the condition has not relapsed within 6 months of completing that course of treatment; AND<br>The condition must have more than 5% blasts in bone marrow; AND<br>The treatment must not be more than 2 treatment cycles under this restriction in a lifetime.<br>According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 9 days of the first cycle and the first 2 days of the second cycle. For all subsequent cycle starts and re-initiation (e.g. if treatment is interrupted for 4 or more hours), supervision by a health care professional or hospitalisation is recommended.<br>An amount of 651 microgram will be sufficient for a continuous infusion of blinatumomab over 28 days in cycle 1. An amount of 784 microgram, which may be obtained under Induction treatment - balance of supply restriction, will be sufficient for a continuous infusion of blinatumomab over 28 days in cycle 2.<br>Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.<br>The authority application must be made in writing and must include:<br>(1) a completed authority prescription form; and<br>(2) a completed Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and<br>(3) date of most recent chemotherapy, and if this was the initial chemotherapy regimen or salvage therapy, including what line of salvage; and<br>(4) if applicable, the date of completion of blinatumomab treatment for measurable residual disease and the date of the patient's subsequent relapse; and<br>(5) the percentage blasts in bone marrow count that is no more than 4 weeks old at the time of application. | Compliance with Written Authority Required procedures |
| C14631 | P14631 | Measurable residual disease of precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL)<br>Initial treatment of measurable residual disease of Pre-B-cell ALL<br>Must be treated by a physician experienced in the treatment of haematological malignancies.<br>Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; AND | Compliance with Written Authority Required procedures |

| | | | |
|---|---|---|---|
| | | The condition must not be present in the central nervous system or testis; AND<br>Patient must have achieved complete remission following intensive combination chemotherapy for initial treatment of acute lymphoblastic leukaemia (ALL) or for subsequent salvage therapy; AND<br>Patient must have measurable residual disease based on measurement in bone marrow, documented after an interval of at least 2 weeks from the last course of systemic chemotherapy given as intensive combination chemotherapy treatment of ALL/as subsequent salvage therapy, whichever was the later, measured using flow cytometry/molecular methods; AND<br>The treatment must not be more than 2 treatment cycles under this restriction in a lifetime.<br>According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 days of the first cycle and the first 2 days of the second cycle.<br>For all subsequent cycle starts and re-initiation (e.g. if treatment is interrupted for four or more hours), supervision by a health care professional or hospitalisation is recommended.<br>An amount of 784 mcg will be sufficient for a continuous infusion of blinatumomab over 28 days in each cycle.<br>Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.<br>The authority application must be made in writing and must include:<br>(1) a completed authority prescription form; and<br>(2) a completed Measurable residual disease positive Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and<br>(3) date of most recent chemotherapy, and if this was the initial chemotherapy regimen or salvage therapy; and<br>(4) the percentage blasts in bone marrow count that is no more than 4 weeks old at the time of application.<br>Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time where an assessment is required must cease PBS-subsidised therapy with this agent. | |

**[8] Schedule 4, after entry for Trastuzumab**

*insert:*

| | | | |
|---|---|---|---|
| Trastuzumab deruxtecan | C14470 | Metastatic (Stage IV) HER2 positive breast cancer<br>Patient must have evidence of human epidermal growth factor (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) in either the primary tumour/a metastatic lesion - establish this finding once only with the first PBS prescription; AND<br>The condition must have progressed following treatment with at least one prior HER2 directed regimen for metastatic breast cancer; OR<br>The condition must have, at the time of treatment initiation with this drug, progressed during/within 6 months following adjuvant treatment with a HER2 directed therapy; AND<br>Patient must have, at the time of initiating treatment with this drug, a WHO performance status no higher than 1; AND<br>The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication; AND<br>The treatment must not be prescribed where any of the following is present: (i) left ventricular ejection fraction of less than 50%, (ii) symptomatic heart failure; confirm cardiac function testing for | Compliance with Authority Required procedures |

| | | |
|---|---|---|
| | the first PBS prescription only.<br>Patient must be undergoing initial treatment with this drug - the following are true: (i) this is the first prescription for this drug, (ii) this prescription seeks no more than 3 repeat prescriptions; OR<br>Patient must be undergoing continuing treatment with drug - the following are true: (i) there has been an absence of further disease progression whilst on active treatment with this drug, (ii) this prescription does not seek to re-treat after disease progression, (iii) this prescription seeks no more than 8 repeat prescriptions.<br>Confirm that the following information is documented/retained in the patient's medical records once only with the first PBS prescription:<br>1) Evidence of HER2 gene amplification (evidence obtained in relation to past PBS treatment is acceptable).<br>2) Details of prior HER2 directed drug regimens prescribed for the patient.<br>3) Cardiac function test results (evidence obtained in relation to past PBS treatment is acceptable). | |