



PB 18 of 2025

National Health (Efficient Funding of Chemotherapy) Special Arrangement Amendment (March 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 24 February 2025

REBECCA RICHARDSON
Assistant Secretary
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 (March Update) Instrument 2025*.
- (2) This instrument may also be cited as PB 18 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. <i>The whole of this instrument</i>	<i>1 March 2025</i>	<i>1 March 2025</i>

Note: This table relates only to the provisions of this instrument as originally made.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Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.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] Subsection 27(3)

omit: 99(3)(b) *substitute:* 99AAAB(1)(b)

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

(a) *omit from the column headed “Circumstances”:* **C14587 C14588 C14631**

(b) *insert in numerical order in the column headed “Circumstances”:* **C16292 C16308 C16334 C16341**

[3] Schedule 1, Part 2, entry for Blinatumomab [Maximum Amount: 651 mcg; Number of Repeats: 0]

omit from the column headed “Purposes”: **P14588** *substitute:* **P16292**

[4] Schedule 1, Part 2, entry for Blinatumomab [Maximum Amount: 784 mcg; Number of Repeats: 1]

omit from the column headed “Purposes”: **P14587 P14631** *substitute:* **P16308 P16334 P16341**

[5] Schedule 2, entry for Mycobacterium bovis (Bacillus Calmette and Guérin), Tice strain

omit from the column headed “Form”: **Vial containing powder for intravesical administration approximately 5 x 10⁸ CFU**

substitute: **Vial containing powder for intravesical administration approximately 500 million CFU**

[6] Schedule 3, Part 1, omit entry for Circumstances Code “C14587”

[7] Schedule 3, Part 1, omit entry for Circumstances Code “C14588”

[8] Schedule 3, Part 1, omit entry for Circumstances Code “C14631”

[9] Schedule 3, Part 1, after entry for Circumstances Code “C16280”

insert:

C16292	P16292	Blinatumomab	Acute lymphoblastic leukaemia Induction treatment 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 The condition must not be present in the central nervous system or testis; AND	Compliance with Written Authority Required procedures
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			<p>Patient must have previously received a tyrosine kinase inhibitor (TKI) if the condition is Philadelphia chromosome positive; AND</p> <p>Patient must have received intensive combination chemotherapy for initial treatment of ALL or for subsequent salvage therapy; AND</p> <p>Patient must not have received more than 1 line of salvage therapy; AND</p> <p>The condition must be one of the following: (i) untreated with this drug for Precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL), (ii) treated with this drug for Pre-B-cell ALL, but the condition has not relapsed within 6 months of completing that course of treatment; AND</p> <p>The condition must have more than 5% blasts in bone marrow; AND</p> <p>The treatment must not be more than 2 treatment cycles under this restriction in a lifetime.</p> <p>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.</p> <p>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.</p> <p>Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) details of the proposed prescription; and</p> <p>(2) a completed Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and</p> <p>(3) date of most recent chemotherapy, and if this was the initial chemotherapy regimen or salvage therapy, including what line of salvage; and</p> <p>(4) if applicable, the date of completion of blinatumomab treatment for Pre-B-cell ALL in CR and the date of the patient's subsequent relapse; and</p> <p>(5) the percentage blasts in bone marrow count that is no more than 4 weeks old at the time of application.</p>	
C16308	P16308	Blinatumomab	<p>Precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL)</p> <p>Continuing treatment of Pre-B-cell ALL in complete haematological remission (CR)</p> <p>Must be treated by a physician experienced in the treatment of haematological malignancies.</p> <p>Patient must have previously received PBS-subsidised treatment with this drug for this condition; AND</p> <p>Patient must have achieved a complete remission; AND</p> <p>The condition must be negative for measurable residual disease (MRD) using the same method used to establish initial MRD status; AND</p>	Compliance with Authority Required procedures

			<p>Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND</p> <p>The treatment must not be more than 2 treatment cycles under this restriction in a lifetime.</p> <p>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.</p> <p>An amount of 784 microgram will be sufficient for a continuous infusion of blinatumomab over 28 days in each cycle.</p> <p>Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.</p> <p>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.</p>	
C16334	P16334	Blinatumomab	<p>Precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL)</p> <p>Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements for Pre-B-cell ALL in complete haematological remission (CR)</p> <p>Must be treated by a physician experienced in the treatment of haematological malignancies.</p> <p>Patient must have commenced treatment with this medicine for this condition prior to 1 March 2025; AND</p> <p>Patient must have had an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1, at initiation of non-PBS-subsidised treatment with this drug; AND</p> <p>The condition must not be present in the central nervous system or testis; AND</p> <p>Patient must have achieved complete remission following intensive combination chemotherapy for initial treatment of acute lymphoblastic leukaemia (ALL) at initiation of non-PBS-subsidised treatment with this drug; OR</p> <p>Patient must have had at initiation of non-PBS-subsidised treatment with this drug: (i) achieved complete remission following intensive combination chemotherapy, (ii) measurable residual disease based on measurement in bone marrow, documented after 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</p> <p>Patient must not have developed disease progression while receiving treatment with this drug for this condition; AND</p> <p>Patient must have received at least 1 treatment cycle of non-PBS therapy under this restriction; AND</p> <p>The treatment must not be more than 4 treatment cycles of therapy (non-PBS and PBS) under this restriction in a lifetime.</p> <p>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.</p> <p>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.</p> <p>An amount of 784 mcg will be sufficient for a continuous infusion of blinatumomab over 28 days in</p>	Compliance with Written Authority Required procedures

			<p>each cycle.</p> <p>Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) details of the proposed prescription; and</p> <p>(2) a completed Acute Lymphoblastic Leukaemia in complete haematological remission PBS Authority Application - Supporting Information Form; and</p> <p>(3) date of most recent chemotherapy, and if this was the initial chemotherapy regimen or salvage therapy; and</p> <p>(4) the percentage blasts in bone marrow count that is no more than 4 weeks old at the time of application.</p> <p>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.</p>	
C16341	P16341	Blinatumomab	<p>Precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL)</p> <p>Initial treatment of Pre-B-cell ALL in complete haematological remission (CR)</p> <p>Must be treated by a physician experienced in the treatment of haematological malignancies.</p> <p>Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; AND</p> <p>The condition must not be present in the central nervous system or testis; AND</p> <p>Patient must have achieved complete remission following intensive combination chemotherapy for initial treatment of acute lymphoblastic leukaemia (ALL); OR</p> <p>Patient must have: (i) achieved complete remission following intensive combination chemotherapy, (ii) measurable residual disease based on measurement in bone marrow, documented after 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</p> <p>The treatment must not be more than 2 treatment cycles under this restriction in a lifetime.</p> <p>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.</p> <p>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.</p> <p>An amount of 784 mcg will be sufficient for a continuous infusion of blinatumomab over 28 days in each cycle.</p> <p>Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) details of the proposed prescription; and</p> <p>(2) a completed Acute Lymphoblastic Leukaemia in complete haematological remission PBS</p>	Compliance with Written Authority Required procedures

<p>Authority Application - Supporting Information Form; and</p> <p>(3) date of most recent chemotherapy, and if this was the initial chemotherapy regimen or salvage therapy; and</p> <p>(4) the percentage blasts in bone marrow count that is no more than 4 weeks old at the time of application.</p> <p>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.</p>
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