ACCESSING BLINCYTO® ON THE PBS

FOR THE TREATMENT OF MRD POSITIVE B-CELL PRECURSOR ALL IN PATIENTS IN COMPLETE HAEMATOLOGICAL REMISSION[1,2]

AUTHORITY REQUIRED[2]

A treatment course consists of up to 2 induction cycles of BLINCYTO® (initial treatment phase), followed by up to 2 consolidation cycles.[1]

INITIAL TREATMENT PHASE[2]

The authority application must be made in writing and must include:

1. A completed authority prescription form;
2. A completed MRD+ ALL PBS Authority Application – Supporting Information Form;
3. Sufficient information to determine the patient's eligibility according to the PBS criteria as follows:

The patient has MRD* with an ECOG performance status 0 or 1

(Note: provide the percentage blasts in bone marrow count that is ≤4 weeks old at the time of application)

↓

AND achieved complete remission following intensive combination chemotherapy for initial treatment of ALL or for subsequent salvage therapy

(Note: provide the date of most recent chemotherapy, and if this was the initial chemotherapy regimen or salvage therapy)

↓

AND the condition must not be present in the central nervous system or testis

- Applications for balance of supply may be made by contacting the Australian Government Department of Human Services on 1800 700 270 (extension 5).
- Patients must not receive more than 2 treatment cycles under the Induction (Initial and Balance of Supply) restrictions.

*Defined as $\geq 10^{-4}$ (0.01%) blasts based on measurement in bone marrow, documented after an interval of ≥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.

References: 1. BLINCYTO® (blinatumomab) Product Information. www.amgen.com.au/Blincyto.PI **2.** Pharmaceutical Benefits Scheme. Available at: www.pbs.gov.au (accesed January 2020).

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CONTINUING TREATMENT[2]

After a written authority application for induction treatment has been approved, application for continuing treatment can be made by calling 1800 700 270 (extension 5) Monday to Friday between 8.00 am and 5.00 pm, Australian Eastern Standard Time.

To be eligible for continuing treatment, all applications must demonstrate:

Patient must have previously received PBS-subsidised induction treatment with this drug for this condition

↓

AND have demonstrated a complete remission

↓

AND be MRD negative*

*Either undetectable using the same method used to determine original eligibility or $<10^{-4}$ (0.01%) blasts based on measurement in bone marrow.

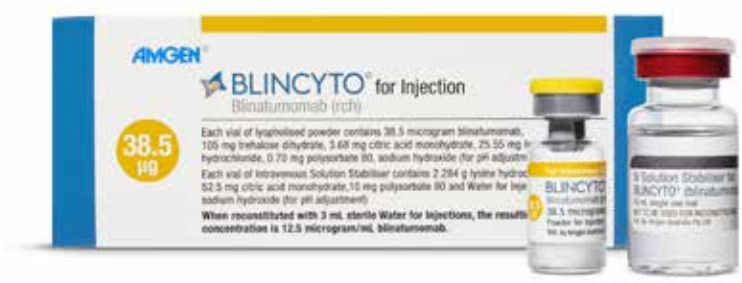
↓

AND not developed disease progression while receiving PBS-subsidised treatment with this drug for this condition

↓

AND treatment must not exceed 2 treatment cycles under this restriction in a lifetime

Note: BLINCYTO® is not PBS subsidised if administered to an in-patient in a public hospital setting.



BLINCYTO® (blinatumomab)

References: 1. BLINCYTO® (blinatumomab) Product Information. www.amgen.com.au/Blincyto.PI **2.** Pharmaceutical Benefits Scheme. Available at: www.pbs.gov.au (accesed January 2020).

BLINCYTO®
(blinatumomab)

For more information on BLINCYTO® or to report any adverse events or product complaints involving BLINCYTO® please contact Australia Medical Information on 1800 803 638

PBS Information: Section 100 listed. Authority required.
Refer to PBS Schedule for full Authority listing.

***WARNING*:** *The following have occurred in patients receiving BLINCYTO®:*
• Cytokine Release Syndrome, which may be life-threatening or fatal • Neurological toxicities, which may be severe, life-threatening, or fatal • Reactivation of JC viral infection
Interrupt or discontinue BLINCYTO® as recommended if any of these adverse events occur
(See Section 4.4 Special warnings and precautions for use and Section 4.2 Dose and method of administration).

REFER TO FULL PRODUCT INFORMATION BEFORE PRESCRIBING; AVAILABLE FROM AMGEN AUSTRALIA PTY LTD, PH: 1800 803 638 OR AT WWW.AMGEN.COM.AU/BLINCYTO.PI

For more information about BLINCYTO® or to report an adverse event or product complaints about BLINCYTO®, please contact Amgen Medical Information on 1800 803 638.

BLINCYTO® Minimum Product Information: Indication: treatment of relapsed or refractory (R/R) B-cell precursor acute lymphoblastic leukaemia (ALL); treatment of minimal residual disease (MRD) positive ALL in patients in complete haematological remission. **Contraindications:** hypersensitivity to blinatumomab, CHO-derived proteins or any excipient. **Precautions:** neurologic events; increased risk for serious infections; cytokine release syndrome; infusion reactions; tumour lysis syndrome, pancreatitis. Management of these adverse reactions may require interruption or discontinuation of treatment. Neutropenia and febrile neutropenia; elevated liver enzymes; leukoencephalopathy; medication errors – strictly follow preparation and administration instructions. Pregnancy Category: C. Use contraception during and for 48 hours after treatment. Discontinue breast-feeding during and for at least 48 hours after treatment. Do not use recommended adult fixed dose in paediatric patients. No data in patients aged less than 28 days. **Interactions:** low potential of clinically meaningful drug interaction with BLINCYTO® mediated cytokine elevation. Vaccination with live viral vaccines not recommended 2 weeks prior to or during treatment, and until recovery of B lymphocytes to normal range following last treatment cycle. **Adverse Reactions:** Common: infections, pyrexia, infusion-related reactions, headache, anaemia, febrile neutropenia, neutropenia, thrombocytopenia, oedema, increased liver enzymes, fatigue, nausea, tremor, hypokalaemia, diarrhoea, chills. See also Precautions for serious adverse reactions. **Dosage & Administration:** R/R ALL: Single cycle is 4 weeks continuous intravenous (cIV) infusion then 2 week treatment free interval. *For patients greater than or equal to 45 kg (fixed dose)*: Cycle 1 – starting dose 9 micrograms/day for days 1-7, then 28 micrograms/day for days 8-28. All other cycles 28 micrograms/day for 4 weeks. For patients less than 45 kg (body surface area based dose): Cycle 1 – starting dose 5 micrograms/m^2/day for days 1-7 (do not exceed 9 micrograms/day), then 15 micrograms/m^2/day (do not exceed 28 micrograms/day); all other cycles, 15 micrograms/m^2/day (do not exceed 28 micrograms/day). For maintenance, 28 day cIV infusion, then 56 days treatment free. Hospitalise at least first 9 days of Cycle 1 and first 2 days of Cycle 2. Supervision or hospitalisation for other cycle starts and reinitiation. Adults: premedicate with 20 mg IV dexamethasone prior to initiation of each cycle. Intrathecal chemotherapy prophylaxis recommended before and during therapy. Treat with dexamethasone (≤ 24 mg/day) if high tumour burden. Paediatrics: premedicate with dexamethasone 10 mg/m2 (not to exceed 20 mg) oral or IV 6 to 12 hours prior to start of BLINCYTO® (Cycle 1 day 1), followed by premedication with dexamethasone 5 mg/m^2 oral or IV within 30 minutes of start of BLINCYTO® (Cycle 1 day 1). **MRD+ ALL:** 28 day cIV infusion then 14 days treatment free, for up to 4 cycles; premedicate with prednisone 100 mg IV or equivalent 1 hour prior to start of BLINCYTO® each cycle; hospitalise first 3 days Cycle 1 and first 2 days Cycle 2, supervise/hospital for subsequent cycle starts and reinitiation – see full PI. R/R & MRD+ ALL – Interrupt BLINCYTO® if grade 3 neurological events, Cytokine Release Syndrome or other clinically relevant adverse reactions occur see full PI.

BLINCYTO® (blinatumomab)

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