7.02b BLINATUMOMAB, Powder for I.V. infusion 38.5 micrograms, Blincyto®, Amgen Australia Pty Limited

1 Purpose of Item

1.1 To request an extension to the listing of blinatumomab, which is PBS-listed for the treatment of relapsed or refractory (R/R) Philadelphia chromosome negative (Ph-) B-cell precursor acute lymphocytic leukaemia (B-ALL), to include patients whose condition is Philadelphia chromosome positive (Ph+).

2 Background

2.1 Inotuzumab was recommended for the treatment of R/R Ph- B-ALL at the November 2018 meeting on a cost-minimisation basis against blinatumomab. At the November 2018 meeting, the PBAC considered there is a high clinical need in patients with Ph+ R/R disease and noted that the INO-VATE ALL trial included patients with Ph+ disease (inotuzumab PSD, November 2018, paragraph 7.3).

2.2 At the March 2019 meeting, the PBAC considered a proposal from the sponsor of inotuzumab regarding the likely financial implications of extending the recommended listing of inotuzumab to include patients with Ph+ R/R B-ALL. The PBAC deferred its decision to enable further work on the restriction and financial estimates. Further, the PBAC advised that it would welcome a similar proposal from the sponsor of blinatumomab, and considered that the extension of the inotuzumab and blinatumomab listings should be progressed in parallel (Paragraphs 4.1 and 4.2, inotuzumab Public Summary Document (PSD), March 2019).

2.3 Correspondence was received from the sponsor of blinatumomab on 17 April 2019 seeking an extension of the current listing to include patients whose condition is Ph+.

3 Requested listing

3.1 The blinatumomab sponsor proposed the following changes to the restrictions for induction treatment (i.e. induction and balance of supply):

- Removal of: "The condition must be Philadelphia chromosome negative";
- Addition of: "If the condition is expressing the Philadelphia chromosome, initial or salvage therapy must also have included a later-generation tyrosine kinase inhibitor (TKI)"; and
- Addition of a requirement, in the Prescriber Instruction, that the written authority application must include "If the condition is expressing the Philadelphia chromosome, date and name of the most recent later-generation tyrosine kinase inhibitor therapy".

3.2 The PBAC noted the proposed restriction criteria "If the condition is expressing the Philadelphia chromosome, initial or salvage therapy must also have included a later-generation tyrosine kinase inhibitor (TKI)" would exclude patients in first salvage who received imatinib as initial first-line treatment. As such, the PBAC recommended limiting the use of blinatumomab and inotuzumab to Ph+ patients previously treated with a TKI without specifying that the TKI is 'later-generation'. In this regard, the PBAC also recommended that the proposed Prescriber Instruction "If the condition is expressing the Philadelphia chromosome, date and name of the most recent later-generation tyrosine kinase inhibitor therapy" be excluded from the restriction.

3.3 At the March 2019 meeting, the PBAC considered that for a small proportion of patients it may be clinically appropriate for inotuzumab to be used in combination with a TKI (Paragraph 4.6, inotuzumab PSD, March 2019).

3.4 The sponsor stated that it "supports a small number of R/R Ph+ patients with compassionate supply of blinatumomab" and thus requested a grandfathering restriction with the same eligibility criteria outlined above.

4 Estimated PBS usage & financial implications

4.1 Table 1 outlines the financial impact of listing both blinatumomab and inotuzumab for Ph+ patients as estimated by the sponsor of blinatumomab. The utilisation split between blinatumomab and inotuzumab was not estimated. The sponsor stated that the utilisation split should not matter given inotuzumab was recommended on a cost-minimisation basis to blinatumomab.

4.2 The financial estimates assumed that blinatumomab and inotuzumab would be subsidised for use in first- and second-line salvage. In its March 2019 consideration of inotuzumab for Ph+ patients (which did not assume use in first-line salvage), the PBAC advised that it may be appropriate for the financial estimates to account for use in first-line salvage, although this use was expected to be small for inotuzumab (Paragraph 4.8, inotuzumab PSD, March 2019).

Table 1: Estimated financial impact of blinatumomab and inotuzumab for Ph+ R/R B-ALL patients

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Ph- patients - currently eligible R/R Ph- population						
Adults						
Paediatrics						
Ph+ patients with R/R B-ALL – requested population						
Eligible **Ph+** adults (23% of B-ALL)[a]						
Eligible **Ph+** paediatrics (5% of B-ALL)[b]						
Uptake rate of blina or inotuz [c]	80%	80%	80%	80%	80%	80%
Patients treated with 1 biologic (blina or inotuz)						
Patients treated with second biologic (blina or inotuz) [d]						
Total courses of blina or inotuz						
Total cost to the PBS/RPBS	$	$	$	$	$	$
Total PBS/RPBS cost for Ph- and Ph+ for blina and inotuz	$	$	$	$	$	$

Abbreviations: B-ALL, B-cell precursor acute lymphoblastic leukaemia; blina, blinatumomab; inotuz = inotuzumab; PBS, Pharmaceutical Benefits Scheme; Ph+, Philadelphia chromosome positive; Ph-, Philadelphia chromosome negative; RPBS, Repatriation Schedule of Pharmaceutical Benefits; R/R, relapsed/refractory

Source: 'Blinatumomab financial estimates_From sponsor.xlsx'; Table 1, Inotuzumab PBAC Minutes March 2019

[a] Assumes 23% of patents with B-ALL are Ph+. The number of R/R patients was based on the same assumption as agreed for Ph- patients (i.e. of newly diagnosed B-ALL patients, 39% of patients are cured in the newly diagnosed setting, 11% of are primary refractory and 50% relapse in the following year).

[b] Separate revised assumptions were made for paediatric patients: 5% of paediatric patients were assumed to be Ph+; and a higher proportion of paediatric patients (85%) were assumed to be cured in the newly diagnosed setting (i.e. fewer R/R). The sponsor assumed 4% of paediatric patients are primary refractory and 11% relapse in following year.

[c] Uptake for Ph+ patients was assumed to be the same as accepted for eligible Ph- patients.

[d] Estimates of the extent of sequential blinatumomab and inotuzumab use were based on advice from the Inotuzumab November 2018 Public Summary Document (i.e. 50% of patients will receive both blinatumomab and inotuzumab).

The redacted table shows that at Year 6, the estimated number of patients was less than 10,000 per year and the total cost to the PBS/RPBS for listing both blinatumomab and inotuzumab for Ph+ R/R B-ALL patients would be less than $10 million per year.

4.3 The sponsor (of blinatumomab) estimated that the cost to the PBS/RPBS of listing both blinatumomab and inotuzumab for Ph+ patients would be less than $10 million in Year 6 and between $10 – $20 million over six years. The sponsor stated that cost offsets due to reduced PBS chemotherapy costs and reduced MBS administration costs were estimated to be less than $10 million, thus the sponsor estimated a total cost of $10 – $20 million over six years.

4.4 The PBAC noted that the estimates provided by the blinatumomab sponsor appropriately included both blinatumomab and inotuzumab, and also appropriately included use in first-line salvage.

5 PBAC Outcome

5.1 The PBAC recommended extending the listings of blinatumomab and inotuzumab to include patients with Ph+ disease on the basis that it considered blinatumomab and inotuzumab would be sufficiently effective and cost-effective in patients with Ph+ disease. The PBAC considered the financial impact of amending the restrictions for both drugs would be relatively small compared to the Ph- population.

5.2 The PBAC reaffirmed there is a high clinical need in patients with Ph+ disease (R/R B-ALL) particularly given it is generally associated with a poorer prognosis than Ph- disease.

5.3 The PBAC considered that overall, the treatment effect of blinatumomab was unlikely to differ significantly based on Philadelphia chromosome status. On this basis, the PBAC was satisfied that blinatumomab and inotuzumab would be sufficiently cost-effective in Ph+ disease.

5.4 The PBAC reiterated its previous consideration that the extension of both inotuzumab and blinatumomab listings should be progressed in parallel (Paragraph 4.2, inotuzumab PSD, March 2019).

5.5 The PBAC considered that it may be clinically appropriate for blinatumomab or inotuzumab to be used in combination with a TKI.

5.6 Given TKIs are standard care in previously untreated Ph+ B-ALL (initial first-line treatment), the PBAC considered it would be appropriate to limit use of blinatumomab and inotuzumab to Ph+ patients previously treated with a TKI.

5.7 The PBAC considered that the restrictions for inotuzumab and blinatumomab should align where possible.

5.8 The PBAC noted the financial impact of extending the current listings of blinatumomab and inotuzumab to Ph+ R/R B-ALL patients was likely to be small relative to the Ph- patient population given the small number of patients. The PBAC considered that the underlying assumptions used by the sponsor of blinatumomab to estimate utilisation of both blinatumomab and inotuzumab in Ph+ patients (in first- and second-line salvage) were reasonable noting that the estimates generally aligned with those provided for inotuzumab in second-line salvage in the March 2019 meeting.

5.9 The PBAC considered that the existing RSAs for blinatumomab and inotuzumab would need to be updated to include the estimated cost of treatment of new patients with Ph+ disease. The PBAC noted that any increase to the associated financial caps should only be based on the number of additional treatment courses expected with the extension of the existing listing to patients with Ph+ disease based on the financial estimates. The PBAC considered that the financial estimates should account for no more than 50% of patients receiving sequential therapy with these agents consistent with its previous advice.

5.10 The PBAC noted that flow-on changes would be required to the existing TKI restrictions to allow use in combination with blinatumomab or inotuzumab.

Outcome:
Recommended

6 Recommended listing

6.1 Amend existing listings:

Name, Restriction, Manner of administration and form	Max. Amt	№.of Rpts	Proprietary Name and Manufacturer	
BLINATUMOMAB 38.5 microgram injection [1 vial] (&) inert substance solution [10 mL vial], 1 pack	651 mcg	0	Blincyto®	Amgen Australia P/L

Category/Program:	S100 – Efficient Funding of Chemotherapy (EFC)
PBS indication:	Acute lymphoblastic leukaemia (ALL)
Treatment phase:	Induction treatment
Restriction:	Authority Required - In Writing
Clinical criteria:	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 ~~The condition must be Philadelphia chromosome negative~~ *Patient must have previously received a tyrosine kinase inhibitor if the condition is Philadelphia chromosome positive,* AND Patient must have received intensive combination chemotherapy for initial treatment of ALL or subsequent salvage therapy, AND Patient must not have received more than 1 line of salvage therapy, AND The condition must have more than 5% blasts in bone marrow, AND The treatment must not be more than 2 treatment cycles under this restriction in a lifetime.
Prescriber instructions:	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. 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. Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting. The authority application must be made in writing and must include:

	(1) a completed authority prescription form; (2) a completed Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and (3) date of most recent chemotherapy, and if this was the initial chemotherapy regimen or salvage therapy, including what line of salvage; and (4) a copy of the most recent bone marrow biopsy report of no more than one month old at the time of application.
Administrative advice	Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Complex Drugs Programs Reply Paid 9826 HOBART TAS 700 No increase in the maximum quantity or number of units may be authorised. No increase in the maximum number of repeats may be authorised. Special Pricing Arrangements apply.
Cautions:	Careful monitoring of patients is required due to risk of developing life-threatening Cytokine Release Syndrome, neurological toxicities and reactivation of John Cunningham virus (JC) viral infection.

Category/Program:	S100 – Efficient Funding of Chemotherapy (EFC)
PBS indication:	Acute lymphoblastic leukaemia (ALL)
Treatment phase:	Induction treatment – balance of supply
Restriction:	Authority Required - Telephone
Clinical criteria:	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 ~~The condition must be Philadelphia chromosome negative~~ *Patient must have previously received a tyrosine kinase inhibitor if the condition is Philadelphia chromosome positive,* AND Patient must have received insufficient therapy with this agent for this condition under the Induction treatment restriction to complete a maximum of 2 treatment cycles in a lifetime.

Prescriber instructions:	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. An amount of 784 mcg will be sufficient for a continuous infusion of blinatumomab over 28 days in cycle 2. Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.
Administrative advice	Applications for authorisation under this criterion may be made by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). No increase in the maximum quantity or number of units may be authorised. No increase in the maximum number of repeats may be authorised. Special Pricing Arrangements apply.
Cautions:	Careful monitoring of patients is required due to risk of developing life-threatening Cytokine Release Syndrome, neurological toxicities and reactivation of John Cunningham virus (JC) viral infection.

Name, Restriction, Manner of administration and form	**Max. Amt**	**№.of Rpts**	**Proprietary Name and Manufacturer**	
INOTUZUMAB OZOGAMICIN				
1 mg injection, 1 vial	3384 mcg	2	Besponsa®	Pfizer Australia P/L

Category/Program:	S100 – Efficient Funding of Chemotherapy (EFC)
PBS indication:	Acute lymphoblastic leukaemia (ALL)
Treatment phase:	Induction treatment
Restriction:	Authority Required - In Writing
Clinical criteria:	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 Patient must have received intensive combination chemotherapy for initial treatment of ALL or subsequent salvage therapy, AND Patient must not have received more than 1 line of salvage therapy, AND ~~The condition must be Philadelphia chromosome negative~~ *Patient must have previously received a tyrosine kinase inhibitor if the condition is Philadelphia chromosome positive,* AND The condition must be CD22-positive, AND The condition must have more than 5% blasts in bone marrow, AND The treatment must not be more than 3 treatment cycles under this restriction in a lifetime.
Prescriber instructions:	This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.

	The authority application must be made in writing and must include: (1) two completed authority prescription forms; (2) a completed Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and (3) evidence that the condition is CD22-positive; and (4) date of most recent chemotherapy, and if this was the initial chemotherapy regimen or salvage therapy, including what line of salvage; and (5) a copy of the most recent bone marrow biopsy report of no more than one month old at the time of application. The treatment must not exceed 0.8mg per m2 for the first dose of a treatment cycle (Day 1), and 0.5mg per m2 for subsequent doses (Days 8 and 15) within a treatment cycle. Treatment with this drug for this condition must not exceed 6 treatment cycles in a lifetime.
Administrative advice	Patients are eligible to receive a loading dose for the first dose of a treatment cycle while receiving induction treatment. Two prescriptions are required, the first prescription for the loading dose at a dose no higher than 0.8mg per m2, and the second prescription for two doses at a dose no higher than 0.5mg per m2. Both prescriptions must be submitted with the initial application. Once a patient achieves complete remission or complete remission with partial haematological recovery, a new prescription must be written under the consolidation treatment phase. A complete remission is defined as bone marrow blasts of less than or equal to 5%, no evidence of disease and a full recovery of peripheral blood counts with platelets of greater than 100,000 per microliter, and absolute neutrophil count (ANC) of greater than 1,000 per microliter. A complete remission with partial haematological recovery is defined as bone marrow blasts of less than or equal to 5%, no evidence of disease and a partial recovery of peripheral blood counts with platelets of greater than 50,000 per microliter, and absolute neutrophil count (ANC) of greater than 500 per microliter. Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time when an assessment is required must cease PBS-subsidised therapy with this agent. Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services

	Complex Drugs Programs Reply Paid 9826 HOBART TAS 7001
Cautions:	Careful monitoring of patients is required due to risk of developing life-threatening Cytokine Release Syndrome, neurological toxicities and reactivation of John Cunningham virus (JC) viral infection.

Category/Program:	S100 – Efficient Funding of Chemotherapy (EFC)
PBS indication:	Acute lymphoblastic leukaemia (ALL)
Treatment phase:	Induction treatment
Restriction:	Authority Required - In Writing
Clinical criteria:	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 Patient must have received intensive combination chemotherapy for initial treatment of ALL or subsequent salvage therapy, AND Patient must not have received more than 1 line of salvage therapy, AND ~~The condition must be Philadelphia chromosome negative~~ *Patient must have previously received a tyrosine kinase inhibitor if the condition is Philadelphia chromosome positive,* AND The condition must be CD22-positive, AND The condition must have more than 5% blasts in bone marrow, AND The treatment must not be more than 3 treatment cycles under this restriction in a lifetime.
Prescriber instructions:	This drug is not PBS-subsidised if it is administered to an in-patient in a public hospital setting. The authority application must be made in writing and must include: (1) two completed authority prescription forms; (2) a completed Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and (3) evidence that the condition is CD22-positive; and (4) date of most recent chemotherapy, and if this was the initial chemotherapy regimen or salvage therapy, including what line of salvage; and (5) a copy of the most recent bone marrow biopsy report of no more than one month old at the time of application. The treatment must not exceed 0.8mg per m2 for the first dose of a treatment cycle (Day 1), and 0.5mg per m2 for subsequent doses (Days 8 and 15) within a treatment cycle. Treatment with this drug for this condition must not exceed 6 treatment cycles in a lifetime.
Administrative advice	Patients are eligible to receive a loading dose for the first dose of a treatment cycle while receiving induction treatment. Two prescriptions are required, the first prescription for the

	loading dose at a dose no higher than 0.8mg per m2, and the second prescription for two doses at a dose no higher than 0.5mg per m2. Both prescriptions must be submitted with the initial application. Once a patient achieves complete remission or complete remission with partial haematological recovery, a new prescription must be written under the consolidation treatment phase. A complete remission is defined as bone marrow blasts of less than or equal to 5%, no evidence of disease and a full recovery of peripheral blood counts with platelets of greater than 100,000 per microliter, and absolute neutrophil count (ANC) of greater than 1,000 per microliter. A complete remission with partial haematological recovery is defined as bone marrow blasts of less than or equal to 5%, no evidence of disease and a partial recovery of peripheral blood counts with platelets of greater than 50,000 per microliter, and absolute neutrophil count (ANC) of greater than 500 per microliter. Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time when an assessment is required must cease PBS-subsidised therapy with this agent. Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Complex Drugs Programs Reply Paid 9826 HOBART TAS 7001 No increase in the maximum quantity or number of units may be authorised. No increase in the maximum number of repeats may be authorised. Special Pricing Arrangements apply.
Cautions:	Careful monitoring of patients is required due to risk of developing life-threatening Cytokine Release Syndrome, neurological toxicities and reactivation of John Cunningham virus (JC) viral infection.

Remove the criteria "The treatment must be the sole PBS-subsidised therapy for this condition" from the dasatinib listings (9127J, 9343R, 9126H and 9125G) and ponatinib listings (11453T and 11454W) for acute lymphoblastic leukaemia

6.2 Add new item:

Name, Restriction, Manner of administration and form	**Max. Amt**	**№.of Rpts**	**Proprietary Name and Manufacturer**	
BLINATUMOMAB 38.5 microgram injection [1 vial] (&) inert substance solution [10 mL vial], 1 pack	651 mcg	0	Blincyto®	Amgen Australia P/L

Category/Program:	S100 – Efficient Funding of Chemotherapy (EFC)
PBS indication:	Acute lymphoblastic leukaemia (ALL)
Treatment phase:	Grandfather treatment
Restriction:	Authority Required - In Writing
Clinical criteria:	*Patient must have a documented history of relapsed or refractory B-precursor cell ALL, with an Eastern Cooperative Oncology Group (ECOG) performance status of 2 or less,* *AND* *Patient must have a documented history of receiving intensive combination chemotherapy for initial treatment of ALL or for subsequent salvage therapy,* *AND* *Patient must not have received more than 1 line of salvage therapy,* *AND* *Patient must have a documented history of more than 5% blasts in bone marrow,* *AND* *Patient must have received treatment with this drug for this condition prior to <listing date>* *AND* *Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.*
Prescriber instructions:	*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.* *Blinatumomab is not PBS-subsidised if it is administered to an in-patient in a public hospital setting.* *A patient may qualify for PBS-subsidised treatment under this restriction once only.* *Treatment with this drug for this condition must not exceed 5 treatment cycles in a lifetime.* *Patients who have received up to two treatment cycles as induction therapy with this drug for this condition prior to <listing date> must have achieved a complete remission or a complete remission with partial haematological recovery in order to continue with PBS-subsidised treatment with this drug.* *Patients who have received at least one treatment cycle as consolidation therapy with this drug for this condition prior to <listing date> must have achieved a complete remission or a complete remission with partial haematological recovery in order to continue with PBS-subsidised treatment with this drug.*

	Patients who fail to demonstrate a complete remission (CR) or complete remission with incomplete haematological recovery (CRi) after 2 cycles of PBS-subsidised treatment with this agent must cease PBS-subsidised treatment with this agent. *The authority application must be made in writing and must include:* *(1) a completed authority prescription form;* *(2) a completed Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and* *(3) date of the most recent blinatumomab dose, if this was for induction or consolidation therapy, an how many treatment cycle(s) of PBS-subsidised blinatumomab will be required for completion of induction or consolidation therapy; and* *(4) date of most recent chemotherapy prior to receiving non-PBS subsidised blinatumomab, and if this was the initial chemotherapy regimen or salvage therapy, including what line of salvage; and* *(5) a copy of the most recent bone marrow biopsy report prior to receiving non-PBS subsidised blinatumomab.*
Administrative advice	*A complete remission is defined as bone marrow blasts of less than or equal to 5%, no evidence of disease and a full recovery of peripheral blood counts with platelets of greater than 100,000 per microliter, and absolute neutrophil count (ANC) of greater than 1,000 per microliter.* *A complete remission with partial haematological recovery is defined as bone marrow blasts of less than or equal to 5%, no evidence of disease and a partial recovery of peripheral blood counts with platelets of greater than 50,000 per microliter, and absolute neutrophil count (ANC) of greater than 500 per microliter.* *Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).* *Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au* *Applications for authority to prescribe should be forwarded to:* *Department of Human Services* *Complex Drugs Programs* *Reply Paid 9826* *HOBART TAS 7001* *No increase in the maximum number of repeats will be allowed for completion of induction therapy.* *An increase in the maximum number of repeats of up to 2 will be allowed for completion of consolidation therapy.*

	No increase in the maximum quantity or number of units may be authorised. *Special Pricing Arrangements apply.*
Cautions:	*Careful monitoring of patients is required due to risk of developing life-threatening Cytokine Release Syndrome, neurological toxicities and reactivation of John Cunningham virus (JC) viral infection.*

7 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

8 Sponsor's Comment

Amgen is pleased that blinatumomab will be available on the PBS for patients with Ph+ acute lymphoblastic leukaemia.