7.05 LONCASTUXIMAB TESIRINE, Powder for I.V. infusion 10 mg, Zynlonta®, Swedish Orphan Biovitrum Pty Ltd.

1 Purpose

1.1 The early re-entry resubmission requested a Section 100 Efficient Funding of Chemotherapy listing for loncastuximab tesirine for the treatment of adult patients with relapsed or refractory (R/R) large B-cell lymphoma (LBCL) who have received two or more prior lines of therapy.

1.2 The resubmission was based on the PBAC decision to not recommend loncastuximab tesirine for this indication from its March 2026 meeting. Table 1 outlines how the resubmission addressed the issues raised by PBAC.

Table 1: Summary of key matters to be addressed

Matter of concern	Response	Addressed?
Use of the Sub-Committees' revised base case economic evaluation with a price reduction to achieve an ICER of up to $[redacted][1] per QALY gained (paragraph 7.13, loncastuximab tesirine PBAC PSD, March 2026 PBAC Meeting).	The resubmission presented an updated cost-effectiveness analysis model, utilising the sub-committees' revised base case with a price reduction (to EMP $[redacted]) to achieve an ICER of less than $[redacted][1] per QALY gained.	Yes
An RSA informed by the financial estimates included in the submission i.e. approximately [redacted][3] patients treated over the first 6 years. The PBAC considered, based on the price reduction and number of patients treated, the RSA should ensure the PBS expenditure for loncastuximab does not exceed approximately $[redacted][2] over 6 years (compared with $[redacted][2] in the submission) (paragraph 7.13, loncastuximab tesirine PBAC PSD, March 2026 PBAC Meeting).	The resubmission incorporated a price reduction of loncastuximab tesirine which equated to a net financial impact of less than $[redacted][2] over 6 years. The resubmission proposed to reimburse [redacted]% of expenditure over the RSA caps (meaning that PBS expenditure could exceed $[redacted][2] over 6 years).	Partially
The PBAC considered any available results from the confirmatory randomised LOTIS-5 trial should be included in the early re-entry resubmission. The PBAC noted that patients received loncastuximab tesirine as an earlier line of treatment in LOTIS-5, however considered that the results would be informative in the context of the high level of uncertainty associated with the clinical comparison based on the LOTIS-2 study and the corresponding high level of uncertainty for the economic evaluation (paragraph 7.13, loncastuximab tesirine PBAC PSD, March 2026 PBAC Meeting).	The resubmission stated that no new data from LOTIS-5 was available at the time of preparing the resubmission. In addition, the resubmission stated that should further data become available prior to the July 2026 PBAC meeting, this would be provided. LOTIS-5 data were provided in the pre-PBAC response (see paragraph 4.5).	Yes

Source: Table 1.1, pp8-9 of the resubmission and paragraph 7.13, loncastuximab tesirine PBAC Minutes, March 2026 PBAC Meeting.
The redacted values correspond to the following ranges:
[1] *$55,000 to < $75,000*
[2] *$100 million to < $200 million*
[3] *500 to < 5,000*

2 Background

2.1 Loncastuximab tesirine was provisionally approved by the TGA for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma after two or more lines of systemic therapy on 13 April 2026.[1] The provisional registration specifies that loncastuximab tesirine is not indicated for patients with primary central nervous system lymphoma. The provisional registration also states that the decision to approve this indication has been granted on the results from an open-label, uncontrolled Phase 2 study based on the overall response rate and that continued

[1] Therapeutic Goods Administration. (13 April 2026). ZYNLONTA loncastuximab tesirine 10 mg powder for concentrate for solution for infusion vial. https://www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs/PublicHTML/pdfStore.nsf&docid=481165&agid=(PrintDetailsPublic)&actionid=1

approval of this indication depends on verification and description of benefit in confirmatory trials.

2.2 The PICO from the resubmission is presented below. The population for the PICO differed to that presented in March 2026 with the resubmission specifying LBCL rather than diffuse large B-cell lymphoma (DLBCL). In March 2026, the PBAC considered that it was reasonable to include patients with high-grade B-cell lymphoma (HGBL) and primary mediastinal B-cell lymphoma (PMBL) in the eligible population covered by the proposed restriction. As such, the PBAC considered it was reasonable for the restriction indication to state Large B-cell lymphoma rather than DLBCL to incorporate HGBL and PMBL (paragraph 7.4, loncastuximab tesirine PBAC Public Summary Document [PSD], March 2026 PBAC Meeting).

Table 2: Key components of the clinical issue addressed by the resubmission (as stated in the resubmission)

Component	Description
Population	Adults with relapsed or refractory LBCL who have received 2 or more prior lines of therapy
Intervention	Loncastuximab tesirine
Comparator	Rituximab-based chemoimmunotherapy (using R-ICE as a proxy)
Outcomes	Overall response rate (ORR) Overall survival (OS) Progression-free survival (PFS) Duration of response (DOR) Relapse-free survival (RFS) Health-related quality of life (HRQoL) Adverse events
Clinical claim	loncastuximab tesirine is superior to mixed chemoimmunotherapy in terms of effectiveness and superior in terms of safety

Source: Table 1-2 (p10) of the resubmission.
R/R LBCL = relapsed or refractory large B-cell lymphoma; R-ICE = rituximab, ifosfamide, carboplatin, etoposide

For more detail on PBAC's view, see section 5 PBAC outcome.

3 Requested listing

3.1 The resubmission accepted the March 2026 PBAC recommendations that:

- An Authority Required (Telephone/Electronic) listing for initial and grandfathering treatment phases was appropriate with an Authority Required (Streamlined) listing for continuing treatment.
- The continuing and grandfathering treatment phases should have 3 repeats. However, in contrast to the March 2026 PBAC recommendation for the initial treatment phase to have 1 repeat, the resubmission proposed 2 repeats citing the need for the initiation dose to be administered over 2 cycles. The TGA approved Product Information states the recommended dose of loncastuximab tesirine is 0.15 mg/kg every 3 weeks for first 2 cycles, followed by 0.075 mg/kg every 3 weeks for subsequent cycles. As the initial treatment phase covers two infusions, the March 2026 PBAC recommendation for 1

repeat (original script + 1 repeat script) for this treatment phase remains appropriate.

- The following clinical criteria should be included in the restriction "Patient must have previously received treatment with bi-specific T-cell engager for this condition; OR Patient must be unable to receive treatment with bi-specific T-cell engager for this condition". The current epcoritamab listing refers to a bi-specific T-cell engager as a CD20xCD3 bispecific monoclonal antibody.
- The restriction indication state LBCL rather than DLBCL to incorporate HBCL and PMBL. The proposed initial and grandfathering indications stated 'Relapsed or refractory large B-cell lymphoma, including diffuse large B-cell lymphoma, high-grade B-cell lymphoma and primary mediastinal B-cell lymphoma' rather than Relapsed or refractory large B-cell lymphoma alone.

3.2 The restrictions proposed by the resubmission did not include criteria relating to the March 2026 PBAC advice that, consistent with the LOTIS-2 trial, treatment should be limited to a maximum of 12 months (paragraph 7.4, loncastuximab tesirine PBAC PSD, March 2026 PBAC Meeting). In addition, the clinical criteria, prescribing instructions and administrative advice specified in the grandfathering restriction appear to have been repeated in error.

3.3 The resubmission requested a Special Pricing Arrangement (SPA) with a published ex-manufacturer price (EMP) of $29,000 per 10 mL vial and an effective EMP of $[redacted] per 10 mL vial. The effective EMP offered in the resubmission was [redacted]% lower than that offered in the March 2026 submission (EMP $[redacted] per 10 mL vial) and [redacted]% lower than that offered in the March 2026 pre-PBAC response (EMP $[redacted] per 10 mg vial).

For more detail on PBAC's view, see section 5 PBAC outcome.

4 Consideration of the evidence

Sponsor hearing

4.1 There was no hearing for this item.

Consumer inputs

4.2 The PBAC noted and welcomed the input from an organisation (1) via the Office of Health Technology Assessment Consultation Hub. The input from Rare Cancers Australia described the emotional, practical and financial burden of LBCL, particularly in terms of relapse, treatment uncertainty and travel to specialist centres. Current options such as chimeric antigen receptor T-cell (CAR-T) therapy and chemo-immunotherapy followed by autologous stem cell transplant (ASCT) were noted to often require prolonged hospital stays, significant disruption to family routines and add pressure on support networks. The input described loncastuximab tesirine as providing an additional later-line option for patients with limited alternatives, offering

renewed choice and hope after disease progression. Its administration as a 30-minute infusion every three weeks may reduce disruption and help patients maintain greater normality. The input noted that side effects, including rash, sun sensitivity, fever and chills are like those experienced with many other cancer treatments.

Clinical claim

4.3 No additional clinical data were presented in the resubmission.

4.4 The March 2026 submission described loncastuximab tesirine as superior in terms of effectiveness compared to chemoimmunotherapy. In March 2026, the PBAC considered the claim of superior comparative effectiveness was highly uncertain but likely reasonable (paragraph 7.09, loncastuximab tesirine PBAC PSD, March 2026 PBAC Meeting). At that time, the PBAC also considered a claim of non-inferior safety was appropriate (paragraph 7.10, loncastuximab tesirine PBAC PSD, March 2026 PBAC Meeting).

4.5 In response to the March 2026 PBAC request (see Table 1), the pre-PBAC response provided topline results from the confirmatory randomised LOTIS-5 trial. Patients received loncastuximab as an earlier line of treatment in LOTIS-5 compared to the LOTIS-2 study and the treatment regimen differed from the regimen requested in the resubmission. The pre-PBAC noted that the LOTIS-5 trial met its primary endpoint with median progression free survival increased by 1.42 months (loncastuximab plus rituximab [lonca-R] 6.14 months versus rituximab in combination with gemcitabine and oxaliplatin [RGemOx] 4.72 months). There was no difference in overall survival between lonca-R and RGemOx in LOTIS-5. The pre-PBAC response noted the rate of Grade 5 treatment-emergent adverse events (TEAEs) leading to death was higher in the lonca-R arm compared to the RGemOx arm (13.2% vs 4.6%). This was primarily driven by an increased rate of infections. The pre-PBAC response stated that there were no TEAEs leading to death with loncastuximab tesirine monotherapy in LOTIS-2. The pre-PBAC response also noted that no new safety concerns were identified in the Periodic Safety Update Report which included almost 6,000 subjects.

Economic analysis

March 2026 meeting

4.6 The March 2026 submission presented a cost-effectiveness analysis versus rituximab in combination with ifosfamide, carboplatin, and etoposide (R-ICE) with the error corrected base case reporting an ICER of $95,000 to < $115,000 per QALY gained. Based on the Sub-Committee advice, the pre-PBAC response provided a revised base case that removed the half-cycle correction to costs, incorporated a 15 year time horizon, required 100% of comparator patients to receive 3 R-ICE cycles and increased the PF utility value by 10% with the same disutility of progressed disease (PD) versus progression-free (PF) assumed. However, the PBAC noted the Sub-Committee's advice to modify the approach taken to PF patients so that they follow background mortality after 2 years and remove terminal care costs was not incorporated into the pre-PBAC

response base case. The PBAC noted incorporating these additional amendments increased the ICER to $115,000 to < $135,000[2] per QALY gained. The PBAC noted the model continued to rely on the OS hazard ratio (HR) from the MAIC of loncastuximab versus chemoimmunotherapy with this same HR applied to progression-free survival (PFS) and time on treatment (ToT). The PBAC agreed with the Sub-Committees that this introduced significant uncertainty into the model results, given the high uncertainty surrounding the comparative evidence from the MAIC. As such, the PBAC considered that the ICER was high and highly uncertain and considered that this was not adequately resolved with incorporation of the price reduction offered in the pre-PBAC response (paragraph 7.11, loncastuximab tesirine PBAC PSD, March 2026 PBAC Meeting).

4.7 In March 2026, the PBAC considered the outstanding issues could be easily resolved in a simple resubmission for loncastuximab tesirine using the early re-entry pathway. At that time the PBAC advised that if the sponsor accepts this pathway, the following changes may address the outstanding issues without requiring further re-evaluation:

- Use of the Sub-Committees revised base case economic evaluation with a price reduction to achieve an ICER of up to $55,000 to < $75,000 per QALY gained.

July 2026 meeting

4.8 The resubmission provided an updated cost-effectiveness model. The resubmission stated the revised model applied a 15-year time horizon, removed half-cycle corrections from costs, assumed that 100% of patients in the comparator arm receive R-ICE for 3 treatment cycles, increased the progression-free utility value by 10%, allowed progression-free patients to follow background mortality after 2 years and excluded terminal care costs. The approach taken by the resubmission assuming that 100% of patients in the comparator arm receive R-ICE for 3 treatment cycles was correct. The resubmission stated that incorporating the price reduction offered in the resubmission (see paragraph 3.3), the base case ICER for loncastuximab tesirine compared with chemotherapy is $55,000 to < $75,000 per QALY gained.

[2] The March 2026 Sub-Committee revised base case included changes made to column W of 'Model_Cx' worksheet and Cell D21 of 'Settings and Results' worksheet to force all comparator patients to have 3 cycles of R-ICE (footnote c, Table 16, loncastuximab tesirine PBAC PSD, March 2026 PBAC Meeting). During the preparation of this submission overview, it was noted that the change to column W of the 'Model Cx' worksheet involved applying a value of 1.00 for all cycles in this column rather than for the first 3 cycles only. Correction of this approach to apply a value of 1.00 for the first 3 cycles increased the ICER for multivariate analysis (I) in Table 16 of the March 2026 PBAC PSD from the $115,000 to < $135,000 per QALY gained reported above to $135,000 to < $155,000 per QALY gained.

Table 3 Results of base case analysis

Component	Loncastuximab tesirine	Comparator	Increment
July 2026 resubmission (EMP $[redacted])			
Costs	$[redacted]	$31,725.35	$[redacted]
QALYs	2.516	1.406	1.110
Incremental cost/extra QALY gained (base case)			**$[redacted][1]**
March 2026 submission (EMP $[redacted])			
Costs	$[redacted]	$91,666.95	$[redacted]
QALYs	3.300	1.822 submission (1.816 error-corrected[a])	1.478 submission (1.484 error-corrected)
Incremental cost/extra QALY gained (base case)			**$[redacted][2] ($[redacted][2] error-corrected)**

Source: Table 3-10, p26 of the resubmission, Table 15, p40 of the loncastuximab tesirine March 2026 PBAC Minutes

[a] An error was identified during the March 2026 evaluation in summing QALYs, the disutility of AEs was excluded in calculating total QALYs for the comparator arm.

The redacted values correspond to the following ranges:

[1] *$55,000 to < $75,000*

[2] *$95,000 to < $115,000*

Estimated PBS usage & financial implications

March 2026 meeting

4.9 In March 2026, the PBAC noted that an epidemiological approach was used to estimate the extent of use and financial implications of listing loncastuximab tesirine. The PBAC noted the Sub-Committee considered that the financial implications were underestimated and suggested changes to incorporate increased uptake rates, a prevalent pool of patients and an increase in the proportion of incident patients entering 3L treatment (see Table 20, loncastuximab tesirine PBAC PSD, March 2026 PBAC Meeting). The PBAC acknowledged the pre-PBAC response argument that a substantial proportion of 3L patients continue to receive treatment through clinical trials and hence the uptake rate proposed by the Sub-Committees was likely to reflect the upper limit of loncastuximab tesirine use (paragraph 7.12, loncastuximab tesirine PBAC PSD, March 2026 PBAC Meeting).

4.10 In March 2026, the PBAC considered that the following changes may address the outstanding issues without requiring further re-evaluation:

- A risk sharing arrangement (RSA) informed by the financial estimates included in the submissions i.e. approximately 500 to < 5,000 patients treated over the first 6 years (see shaded section of Table 4). The PBAC considered, based on the price reduction and number of patients treated, the RSA should ensure the PBS expenditure for loncastuximab does not exceed approximately $100 million to < $200 million over 6 years (paragraph 7.13, loncastuximab tesirine PBAC PSD, March 2026 PBAC Meeting).

July 2026 meeting

4.11 As recommended by the PBAC in March 2026, the resubmission provided revised financial estimates which used the same data sources as the March 2026 PBAC submission base case and incorporated the reduced effective price offered for loncastuximab tesirine (see Table 4). The resubmission noted that minor changes to the financial model were made following March 2026 Sub-Committee advice. The changes included reducing the MBS benefit from 85% to 80% and modifying the public/private split from 50/50 to 75/25 to be consistent with the economic model.

4.12 The resubmission estimated the number of treated patients (including grandfathered patients) over 6 years to be 500 to < 5,000. The total cost to the PBS/RPBS of listing loncastuximab tesirine was estimated to be $10 million to < $20 million by Year 6, and a total of $90 million to < $100 million in the first 6 years of listing. The number of patients treated and the estimated PBS/RPBS expenditure over 6 years are consistent with the March 2026 PBAC recommendations.

4.13 The resubmission stated that the sponsor is willing to enter an RSA to mitigate any uncertainty and financial risk to the PBS. The resubmission noted that the updated financial model forecasts total PBS expenditure over 6 years to remain below the $100 million to < $200 million threshold proposed by the PBAC in March 2026 (see paragraph 4.10). The resubmission stated that a [redacted]% rebate above the proposed caps would not be commercially viable. The resubmission proposed an [redacted]% rebate for total expenditure above the annual cap volumes to allow for costs of distribution (including air freight from Europe and cold chain costs). The resubmissions proposal to reimburse [redacted]% of expenditure over the RSA caps may mean that PBS expenditure could exceed $100 million to < $200 million over 6 years if the level of use of loncastuximab tesirine has been underestimated.

Table 4: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
July 2026 resubmission (EMP $[redacted])						
Estimated extent of use						
Number of patients treated - Incident - GF patients	[redacted][1] [redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Number of scripts dispensed	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]
Estimated financial implications						
Cost to PBS/RPBS	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]
Cost to MBS	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]
Net cost to PBS/RPBS/MBS	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]
March 2026 submission (EMP $[redacted])						
Estimated extent of use						
Number of patients treated GF patients	[redacted][1] [redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Number of scripts dispensed	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]
Estimated financial implications						
Net cost to PBS/RPBS	$[redacted][3]	$[redacted][3]	$[redacted][3]	$[redacted][4]	$[redacted][4]	$[redacted][4]
Net cost MBS	$[redacted][5]	$[redacted][5]	$[redacted][5]	$[redacted][5]	$[redacted][5]	$[redacted][5]
Net cost to federal government health budget (PBS/MBS)	$[redacted][3]	$[redacted][3]	$[redacted][3]	$[redacted][4]	$[redacted][4]	$[redacted][4]

Source: Attachment 4.1 – Zynlonta BIM workbook_resumbission, Table 4-15, p34 of the resubmission, Table 19, p48 of the loncastuximab tesirine March 2026 PBAC Minutes

The redacted values correspond to the following ranges:

[1] *< 500*

[2] *500 to < 5,000*

[3] *$20 million to < $30 million*

[4] *$30 million to < $40 million*

[5] *$0 to < $10 million*

For more detail on PBAC's view, see section 5 PBAC outcome.

5 PBAC Outcome

5.1 The PBAC recommended the Section 100 (Efficient Funding of Chemotherapy) Authority Required listing of loncastuximab tesirine for the treatment of adult patients with relapsed or refractory (R/R) large B-cell lymphoma (LBCL) who have received two or more prior lines of therapy. The PBAC was satisfied that loncastuximab tesirine provides, for some patients, a significant improvement in efficacy over rituximab in combination with ifosfamide, carboplatin and etoposide (R-ICE). The PBAC considered that the resubmission had addressed the substantive outstanding issues identified at the March 2026 meeting via the price reduction offered, the updated cost-effectiveness model, the revised financial estimates and the proposed risk sharing arrangement (RSA).

5.2 The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of loncastuximab tesirine would be acceptable

at the price proposed in the resubmission if the following additional measures were implemented:

- An RSA with an [redacted]% rebate for use that exceeds agreed expenditure.

5.3 The PBAC noted the consumer input from Rare Cancers Australia which described the need for additional treatment options for patients unsuitable for, or relapsing after chimeric antigen receptor T-cell (CAR-T) therapy or bispecific therapies. The PBAC also recalled the consumer input from the March 2026 PBAC meeting (paragraph 7.3, loncastuximab tesirine PBAC PSD, March 2026 PBAC Meeting). The PBAC acknowledged the high clinical need in the subgroup of R/R DLBCL patients specified in the submission noting that they have a very poor prognosis.

5.4 In terms of the proposed restriction, the PBAC reiterated that an Authority Required (Telephone/Electronic) listing for initial and grandfathering treatment phases was appropriate with an Authority Required (Streamlined) listing for continuing treatment. The PBAC reiterated that the initial treatment phase should have 1 repeat with 3 repeats for the continuing and grandfathering treatment phases. The PBAC considered the indication 'relapsed or refractory large B-cell lymphoma' was appropriate with no further mention of the subtypes included under this term required. The PBAC considered the terminology 'bispecific T-cell engager' was appropriate for this listing. The PBAC advised that, consistent with the LOTIS-2 trial, treatment should be limited to a maximum of 12 months.

5.5 The PBAC recalled that it had previously considered the claim of superior comparative effectiveness was highly uncertain but likely reasonable and that a claim of non-inferior safety was appropriate (paragraphs 7.09 and 7.10, loncastuximab tesirine PBAC PSD, March 2026 PBAC Meeting). The PBAC noted the pre-PBAC response provided information from the confirmatory randomised LOTIS-5 trial (see paragraph 4.5). The PBAC noted that LOTIS-5 trial met its primary endpoint. The PBAC also noted the rate of Grade 5 treatment-emergent adverse events reported in the LOTIS-5 study. Acknowledging the differences in the line of treatment and the treatment regimens between the LOTIS-2 and LOTIS-5 studies, the PBAC reaffirmed its March 2026 advice regarding the clinical effectiveness and safety claims for loncastuximab tesirine.

5.6 The PBAC noted that, as per its March 2026 advice, the resubmission provided an updated cost-effectiveness model utilising the Sub-committees' revised base case with a price reduction to achieve an ICER of less than $55,000 to < $75,000 per QALY gained. The PBAC considered that this was appropriate.

5.7 The PBAC noted that the resubmission provided revised financial estimates which used the same data sources as the March 2026 PBAC submission base case and incorporated the reduced effective price offered for loncastuximab tesirine in the resubmission. The PBAC considered that the number of patients treated and the estimated PBS/RPBS expenditure over 6 years were consistent with the Committee's March 2026 advice (see paragraph 4.12).

5.8 The PBAC noted the resubmission proposed an RSA based on the revised financial estimates with an [redacted]% rebate for total expenditure above the annual cap volumes. The PBAC advised that the RSA was consistent with its March 2026 advice to share the risk of higher-than-expected patient numbers and considered that an [redacted]% rebate for expenditure above the cap volumes was appropriate.

5.9 The PBAC recommended that loncastuximab tesirine should not be treated as interchangeable on an individual patient basis with any other drugs.

5.10 The PBAC advised that loncastuximab tesirine is suitable for prescribing by medical practitioners only.

5.11 The PBAC recommended that the Early Supply Rule should not apply.

5.12 The PBAC found that the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met. Specifically, the PBAC found that in the circumstances of its recommendation for loncastuximab tesirine:

a) The treatment is not expected to provide a substantial and clinically relevant improvement in efficacy over alternative therapies. The unanchored matching adjusted indirect comparison introduced a high level of uncertainty into the magnitude of benefit (paragraph 7.9, loncastuximab tesirine PBAC PSD, March 2026 PBAC Meeting).

b) The treatment is not expected to address a high and urgent unmet clinical need, as while the clinical need is high in these patients with a poor prognosis, an alternative treatment is available (R-ICE).

c) It was not necessary to make a finding in relation to whether it would be in the public interest for the subsequent pricing application to be progressed under Pricing Pathway A because one or more of the preceding tests had failed.

5.13 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive PBAC recommendation.

Outcome:
Recommended

5.14 Add new item:

Initial (induction) treatment phase

MEDICINAL PRODUCT **Form**		**PBS item code**	**Max. Amount**	**№.of Rpts**
LONCASTUXIMAB TESIRINE Injection		NEW (Public) NEW (Private)	20 mg	1
Available brands				
Zynlonta loncastuximab tesirine 10 mg/2 mL, 2mL vial				
Restriction Summary New1 / Treatment of Concept: New2				
Concept ID (for internal Dept. use)		**Category / Program:** Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals		
		Prescriber type: ☒Medical Practitioners		
		Restriction type: ☒Authority Required (telephone/online PBS Authorities system)		
Prescribing rule level		**Administrative Advice:** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.		
		Administrative Advice: No increase in the maximum number of repeats may be authorised.		
		Administrative Advice: Increased maximum amounts can be requested where a patient's weight is greater than 135kg		
		Episodicity: [blank]		
		Severity: Relapsed or refractory		
		Condition: Large B-cell lymphoma		
		Indication: Relapsed or refractory large B-cell lymphoma		
		Treatment Phase: Induction treatment		
		Clinical criteria:		
		The condition must have relapsed, or be refractory to, at least two prior systemic therapies		
		AND		
		Clinical criteria:		
		Patient must have previously received treatment with chimeric antigen receptor-T (CAR-T) cell therapy for this condition; or		
		Patient must currently be unable to receive treatment with CAR-T cell therapy for this condition		
		AND		
		Clinical criteria:		
		Patient must not be eligible for stem cell transplantation		
		AND		
		Clinical criteria:		
		Patient must have previously received treatment with bi-specific T-cell engager for this condition; or		
		Patient must be unable to receive treatment with bi-specific T-cell engager for this condition		
		AND		
		Clinical criteria:		
		Patient must have a WHO performance status of no higher than 2		
		Prescribing Instructions: Prior systemic therapy may include autologous stem cell transplant.		

	Prescribing Instructions: Definition of patients unable to receive treatment with CAR-T cell therapy for this condition include geographical, psychosocial, clinical ineligibility or urgency.

Continuing treatment phases

MEDICINAL PRODUCT Form	**PBS item code**	**Max. Amount**	**№.of Rpts**
LONCASTUXIMAB TESIRINE Injection	NEW (Public) NEW (Private)	10 mg	3
Available brands			
Zynlonta loncastuximab tesirine 10 mg/2 mL, 2mL vial			
Restriction Summary New / Treatment of Concept: New			
Concept ID (for internal Dept. use)	**Category / Program:** Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals		
	Prescriber type: ☒Medical Practitioners		
	Restriction type: ☒Authority Required (STREAMLINED)		
PR rule level	**Administrative Advice:** No increase in the maximum number of repeats may be authorised.		
PR rule level	**Administrative Advice:** Increased maximum amounts can be requested where a patient's weight is greater than 135kg		
	Indication: Relapsed or refractory large B-cell lymphoma		
	Treatment Phase: Continuing treatment		
	Clinical criteria:		
	Patient must have previously received PBS-subsidised treatment with this drug for this condition		
	AND		
	Clinical criteria:		
	The treatment must be discontinued in patients who experience disease progression while on treatment.		
	AND		
	Clinical criteria:		
	The treatment must not exceed a total of 12 cumulative months from the first dose of this drug regardless of if it was PBS/non-PBS subsidised		

Grandfather treatment phases

MEDICINAL PRODUCT Form	**PBS item code**	**Max. Amount**	**№.of Rpts**
LONCASTUXIMAB TESIRINE Injection	NEW (Public) NEW (Private)	10 mg	3
Available brands			
Zynlonta loncastuximab tesirine 10 mg/2 mL, 2mL vial			
Restriction Summary 16467 / Treatment of Concept: 16405			
Concept ID (for internal Dept. use)	**Category / Program:** Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals		
	Prescriber type: ☒Medical Practitioners		
	Restriction type: ☒Authority Required (telephone/online PBS Authorities system)		

Prescribing rule level		**Administrative Advice:** Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.
		Administrative Advice: No increase in the maximum number of repeats may be authorised.
		Administrative Advice: Increased maximum amounts can be requested where a patient's weight is greater than 135kg
		Episodicity: [blank]
		Severity: Relapsed or refractory
		Condition: Large B-cell lymphoma
		Indication: Relapsed or refractory large B-cell lymphoma
		Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements
		Clinical criteria:
		Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to [LISTING DATE]
		AND
		Clinical criteria:
		The condition must have relapsed, or be refractory to, at least two prior systemic therapies, prior to commencing treatment with this drug
		AND
		Clinical criteria:
		Patient must have had a WHO performance status of no higher than 2 prior to commencing treatment with this drug for this condition
		AND
		Clinical criteria:
		Patient must have previously received treatment with chimeric antigen receptor-T (CAR-T) cell therapy for this condition; or
		Patient must have been unable to receive treatment with CAR-T cell therapy for this condition
		AND
		Clinical criteria:
		Patient must not be eligible for stem cell transplantation
		AND
		Clinical criteria:
		Patient must have previously received treatment with bi-specific T-cell engager for this condition; or
		Patient must be unable to receive treatment with bi-specific T-cell engager for this condition
		AND
		Clinical criteria:
		The treatment must be discontinued in patients who experience disease progression while on treatment.
		AND
		Clinical criteria:
		The treatment must not exceed a total of 12 cumulative months from the first dose of this drug regardless of if it was PBS/non-PBS subsidised
		Prescribing Instructions: Prior systemic therapy may include autologous stem cell transplant.
		Prescribing Instructions: Definition of patients unable to receive treatment with CAR-T cell therapy for this condition include geographical, psychosocial, clinical ineligibility or urgency.
		Administrative Advice: Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

	Administrative Advice: This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

These restrictions may be subject to further review. Should there be any changes made to the restriction the sponsor will be informed.

7 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

8 Sponsor's Comment

The sponsor had no comment.