5.15 RITUXIMAB
1,600 mg/13.4 mL, Solution for subcutaneous injection, MabThera®SC, Roche Products Pty Ltd.

1 Purpose of Application

1.1 This minor submission sought the PBS listing of a new presentation of rituximab, suitable for subcutaneous (SC) administration, for patients with chronic lymphocytic leukaemia (CLL).

2 Requested listing

2.1 The submission requested the same PBS listings for rituximab 1,600 mg/13.4 mL SC injection as that of rituximab intravenous (IV) infusion for the treatment of CLL. The proposed listings are presented below, with Secretariat suggested additions in italics:

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer	
RITUXIMAB Solution for subcutaneous injection 1,600 mg/13.4 mL	1,600 mg	4	$[redacted] (Public hospital) $[redacted] (Private hospital)	MabThera® SC	Roche Products Pty Ltd

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	☐ Dental ☒ Medical Practitioners ☐ Nurse practitioners ☐ Optometrists ☐ Midwives
Condition:	Chronic lymphocytic leukaemia (CLL)
Restriction Level / Method:	☐ Restricted benefit ☐ Authority Required - In Writing ☐ Authority Required - Telephone ☐ Authority Required – Emergency ☐ Authority Required - Electronic ☒ Streamlined
Clinical criteria:	The condition must be CD20 positive chronic lymphocytic leukaemia (CLL), AND The treatment must be in combination with chemotherapy.
Administrative Advice	No increase in the maximum number of repeats may be authorised. This drug is not PBS-subsidised for use as monotherapy. *An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab.*

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
RITUXIMAB Solution for subcutaneous injection 1,600 mg/13.4 mL	1,600 mg	4	$[redacted] (Public hospital) $[redacted] (Private hospital)	MabThera® SC Roche Products Pty Ltd

Category / Program	Section 100 – Efficient funding of Chemotherapy (Schedule 2 – related pharmaceutical benefits)
Prescriber type:	☐ Dental ☒ Medical Practitioners ☐ Nurse practitioners ☐ Optometrists ☐ Midwives
Condition:	Chronic lymphocytic leukaemia (CLL)
Restriction Level / Method:	☐ Restricted benefit ☐ Authority Required - In Writing ☐ Authority Required - Telephone ☐ Authority Required – Emergency ☐ Authority Required - Electronic ☒ Streamlined
Clinical criteria:	The condition must be CD20 positive chronic lymphocytic leukaemia (CLL), AND The treatment must be in combination with chemotherapy.
Administrative Advice	No increase in the maximum number of repeats may be authorised. This drug is not PBS-subsidised for use as monotherapy. *An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab.*

2.2 The submission requested both General Schedule and Section 100 (Efficient Funding of Chemotherapy (EFC): Schedule 2) listings for rituximab SC for the treatment of CLL.

2.3 The requested CLL indication is consistent with the TGA registered indication.

2.4 The submission proposed 4 repeats based on a CLL treatment course comprised of six, four-weekly cycles. As the first dose of rituximab must be administered IV, a maximum of five cycles can be administered SC.

2.5 In the Pre-PBAC response (p1) the sponsor accepted the Secretariat's suggested inclusion of the following wording in the restriction; An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab.

For more detail on PBAC's view, see section 7 "PBAC outcome"

3 Background

3.1 Rituximab 1,600 mg/13.4 mL SC was TGA registered on 26 November 2016 for the treatment of patients with CD20 positive CLL in combination with chemotherapy.

3.2 Rituximab SC (1,400 mg/11.7 mL) was considered by PBAC in November 2014 for the treatment of:

- previously untreated, CD20 positive, diffuse large B-cell non-Hodgkin's lymphoma, in combination with chemotherapy;
- Treatment of symptomatic patients with previously untreated, CD20 positive, Stage III or IV, follicular, B-cell non-Hodgkin's lymphoma, in combination with chemotherapy;
- Relapsed or refractory low-grade B-cell non-Hodgkin's lymphoma;
- Relapsed or refractory follicular B-cell non-Hodgkin's lymphoma.

3.3 Rituximab 1,600 mg/13.4 mL SC has not previously been considered by the PBAC.

3.4 Rituximab IV for the treatment of CD20 positive, CLL, in combination with chemotherapy, was considered by PBAC in November 2010.

For more detail on PBAC's view, see section 7 "PBAC outcome"

4 Clinical place for the proposed therapy

4.1 Rituximab exerts its anti-lymphoma activity by binding to CD20 and mediating B-cell lysis.

4.2 The submission claimed that rituximab SC offers a convenient alternative to the IV formulation.

For more detail on PBAC's view, see section 7 "PBAC outcome"

5 Comparator

5.1 The minor submission nominated rituximab IV 500 mg/m^2 as the comparator.

For more detail on PBAC's view, see section 7 "PBAC outcome"

6 Consideration of the evidence

Sponsor hearing

6.1 There was no hearing for this item as it was a minor submission.

Consumer comments

6.2 The PBAC noted that no consumer comments were received for this item.

Clinical trials

6.3 The minor submission presented the results of one trial, SAWYER, comparing the pharmacokinetics, efficacy and safety of rituximab (1,600 mg/13.4 mL) SC to rituximab IV in patients with previously untreated CLL. This was a two-part open-label randomised trial.

- Part 1 objective: to confirm that selected SC doses of rituximab resulted in C_{trough} levels comparable to rituximab IV;
- Part 2 objective: to establish non-inferiority in pharmacokinetic values, efficacy and safety between the proposed rituximab SC dose (1,600 mg) and the reference rituximab IV dose (500 mg/m^2).

6.4 Details of the SAWYER trail, as provided in the submission, are presented in the table below

Table 1. Trials and associated reports presented in the submission

Trial ID	Protocol title/ Publication title	Publication citation
Direct randomised trials		
SAWYER	Assouline S, Buccheri V, Delmer A, et al. Pharmacokinetics and safety of subcutaneous rituximab plus fludarabine and cyclophosphamide for patients with chronic lymphocytic leukaemia.	British journal of clinical pharmacology. 2015;80(5):1001-9.
	Assouline S, Buccheri V, Delmer A, et al. Pharmacokinetics, safety, and efficacy of subcutaneous versus intravenous rituximab plus chemotherapy as treatment for chronic lymphocytic leukaemia (SAWYER): a phase 1b, open-label, randomised controlled non-inferiority trial.	The Lancet Haematology. 2016;3(3):e128-e38.
	SAWYER CSR. Primary Clinical Study Report – BO25341 – An adaptive, comparative, randomized, parallel-group, multi-center, Phase Ib study of subcutaneous (SC) rituximab versus intravenous (IV) rituximab both in combination with chemotherapy (fludarabine and cyclophosphamide), in patients with previously untreated CLL.	Report No. 1047897. 2014.
	SAWYER CSR. Update Clinical Study Report – BO25341 – An adaptive, comparative, randomized, parallel-group, multi-center, Phase Ib study of subcutaneous (SC) rituximab versus intravenous (IV) rituximab both in combination with chemotherapy (fludarabine and cyclophosphamide), in patients with previously untreated CLL.	Report No. 1071497. 2016

Source: page 15 of the Submission

6.5 Geometric ratio of trough serum concentration between rituximab IV infusion and rituximab SC injection was used for the pharmacokinetic study.

Comparative effectiveness

6.6 The results for the primary pharmacokinetic end point C_{trough} in Cycle 5 and the secondary pharmacokinetic endpoint area under the serum concentration-time curve (AUC_T) at Cycle 6 are shown in the table below.

Table 2. Summary of pharmacokinetic endpoints at Cycle 5 and Cycle 6 - SAWYER

	Rituximab IV 500 mg/m²	**Rituximab SC 1,600 mg**	
PK parameter	**Geometric Mean (coefficient of variation %)**		**Adjusted Geometric Mean Ratio (90% confidence interval)**
C_{trough} (µg/mL) at Cycle 5	61.50 (63.9) (N=69)	97.5 (42.6) (N=65)	1.53 (1.27, 1.83)
AUC_T (µg • day/mL) at Cycle 6	3,630 (32.8) (N=58)	4,088 (34.6) (N=51)	1.10 (0.98, 1.24)

Source: page 10 of the Submission
PK = pharmacokinetic; IV = intravenous; SC = subcutaneous

6.7 The submission stated that the clinical development program for rituximab SC was based on the rationale that the rituximab C_{trough} and AUC_T values after rituximab SC, were at least as high as those after IV administration, resulting in a non-inferior degree of target-site saturation which would result in at least the same degree of efficacy as the IV route.

6.8 Results for the efficacy study are shown in tables 3 and 4 below.

Table 3. Summary of tumour response at 3 months follow-up (intent-to-treat population) - SAWYER

Efficacy parameter	Rituximab IV 500 mg/m^2 (N=88)	Rituximab SC 1,600 mg (N=88)
Overall Response Rate, n (%)	71 (80.7)	75 (85.2)
Non-responders, n (%)	17 (19.3)	13 (14.8)
95% CI for response rates	(70.9, 88.3)	(76.1, 91.9)
Difference in response rates (95% CI)	4.55 (-7.2, 16.3)	
p-value (Chi-squared test)	0.4227	
Odds ratio (95% CI)	1.38 (0.63, 3.05)	
Complete response (CR and CRi), n (%)	29 (33.0)	23 (26.1)
95% CI for CR and CRi rates	(23.3, 43.8)	(17.3, 36.6)
Difference in CR and CRi rates (95% CI)	-6.82 (-20.9, 7.3)	
p-value (Chi-squared test)	0.3216	
Odds ratio (95% CI)	0.72 (0.38, 1.38)	
Partial response (PR), n (%)	42 (47.7)	52 (59.1)
95% CI for PR rates	(37.0, 58.6)	(48.1, 69.5)
Difference in PR rates (95% CI)	11.36 (-3.9, 26.7)	
p-value (Chi-squared test)	0.1308	
Odds ratio (95% CI)	1.58 (0.87, 2.87)	
Stable disease (SD)	1 (1.1)	0 (0.0)
95% CI for SD rates	(0.0, 6.2)	(0.0, 4.1)
Progressive disease (PD)	2 (2.3)	2 (2.3)
95% CI for PD rates	(0.3, 8.0)	(0.3, 0.8)
Not evaluated/missing	14 (15.9%)	11 (12.5%)

Source: page 10-11 of the Submission

IV = intravenous; SC = subcutaneous; CI = confidence interval; CR = complete response; Cri = Complete Response with incomplete bone marrow recovery; PR = partial response

6.9 The submission stated that the efficacy results showed that investigator-assessed Overall Response Rates at three months follow-up, were similar in the rituximab SC (85.2%) and IV (80.7%) arms, thereby demonstrating comparable efficacy results for both the rituximab SC and IV formulations.

Table 4. Overview of Time-To-Event Endpoints (intent-to-treat population) - SAWYER

Efficacy parameter	Rituximab IV 500 mg/m^2 (N=88)	Rituximab SC 1,600 mg (N=88)
Progression-Free Survival		
Patients with Event, n (%)	23 (26.1%)	19 (21.6%)
p-value (Wald test)	0.7192	
Hazard ratio (95% CI)	0.89 (0.49, 1.64)	
Event-Free Survival		
Patients with Event, n (%)	29 (33.0%)	22 (25.0%)
p-value (Wald test)	0.3351	
Hazard ratio (95% CI)	0.76 (0.44,1.33)	
Overall Survival		
Patients with Event, n (%)	12 (13.6%)	7 (8.0%)
p-value (Wald test)	0.2789	
Hazard ratio (95% CI)	0.60 (0.24,1.52)	

Source: page 11 of the Submission

IV = intravenous; SC = subcutaneous; CI = confidence interval

6.10 The submission stated that the results of the time-to-event analyses were comparable across the treatment arms with a wide confidence interval crossing 1,

indicating no difference in benefit and comparable efficacy results for both the rituximab SC and IV formulations. The point estimates for all three efficacy parameters appear to favour the rituximab SC formulation as more patients in the rituximab IV arm experienced a progression, relapse or death event. Median times to event were not reached for any endpoint.

6.11 As this was a minor submission, the results above have not been independently verified.

Comparative harms

6.12 Comparisons of adverse events between SC rituximab and IV rituximab are shown in the table below.

Table 5. Overview of adverse events (safety analysis population) - SAWYER

Adverse events	Number of patients (%)	
	Rituximab IV 500mg/m^2 (N=89)	**Rituximab SC 1,600mg (N=85)**
Total patients with at least one AE	81 (91%)	82 (96%)
Total number of AEs	[redacted]	[redacted]
Deaths	4 (4%)	5 (6%)
Patients with at least one		
AE leading to death	2 (2%)	2 (2%)
Serious AE	29 (33%)	25 (29%)
Serious AE leading to withdrawal from treatment	1 (1%)	3 (4%)
Serious AE leading to dose modification/interruption	1 (1%)	1 (1%)
Treatment-related serious AE	[redacted]	[redacted]
AE leading to withdrawal from treatment	7 (8%)	9 (11%)
AE leading to dose modification/interruption	[redacted]	[redacted]
Treatment-related AE	[redacted]	[redacted]
Treatment-related AE leading to withdrawal from treatment	[redacted]	[redacted]
Treatment-related AE leading to dose modification/interruption	26 (29%)	21 (25%)
Severe AE	63 (71%)	59 (69%)

Source: page 11 of the Submission
IV = intravenous; SC = subcutaneous; AE = adverse event

6.13 The submission stated that there were no new clinically relevant safety signals observed with rituximab SC 1,600 mg and overall incidence of adverse events was similar between the SC and IV treatment arms.

Clinical claim

6.14 The submission claimed non-inferior comparative effectiveness and safety of rituximab SC 1,600 mg compared with rituximab IV 500 mg/m^2 formulation.

6.15 The Secretariat noted that these clinical data were evaluated by TGA prior to ARTG registration.

6.16 The PBAC considered that the claim of non-inferior comparative effectiveness compared to rituximab IV was reasonable.

6.17 The PBAC considered that the claim of non-inferior comparative safety compared to rituximab IV was reasonable.

Economic analysis

6.18 The submission proposed a cost-minimised price for the fixed-dose rituximab SC formulation (1,600 mg) to the current rituximab IV formulation at a dose of 500 mg/m^2 utilising the mean body surface area (BSA) of [redacted] m^2 based on Australian CLL patients.

6.19 The minor submission presented the following cost minimisation analysis.

Table 6. Rituximab IV and SC: Cost minimisation analysis

Rituximab ex-manufacturer price per vial (Section 100)		
Vial size	100 mg	500 mg
Ex-manufacturer price (as of February 2017)	$372.85	$1,864.22
Rituximab IV dose (500 mg/m^2 X [redacted] m^2 BSA)	[redacted] mg	
Ex-manufacturer price for [redacted] mg rituximab IV	$[redacted]	
	Public hospital use ([redacted]%)	Private hospital use ([redacted]%)
Mark-ups Additional fees	- $83.22	1.4% $121.30
Rituximab IV price	$[redacted]	$[redacted]
Weighted cost of rituximab IV for average Australian CLL patient	$[redacted]	
Rituximab SC ex-manufacturer price per vial (Section 85)		
Vial size	1,600 mg	
Cost-minimised ex-manufacturer price	$[redacted]	
Rituximab SC dose (fixed dose)	1,600 mg 1 x 1,600 mg vial	
Cost-minimised ex-manufacturer price	$[redacted]	
	Public hospital use ([redacted]%)	Private hospital use ([redacted]%)
Wholesale mark-up Pharmacy mark-up Dispensing fee	11.1% - -	11.1% 1.4% $7.02
Rituximab SC DPMQ	$[redacted]	$[redacted]
Weighted cost of rituximab SC for average Australian CLL patient	$[redacted]	

Note: MABTHERA SC CLL Minor PBAC.xlsx
Source: page 6 of the submission

6.20 The November 2014 submission for rituximab SC 1400 mg used the following methodology to calculate the cost-minimised price (see Table 7).

Table 7. Rituximab IV and SC: Cost minimisation analysis

Rituximab ex-manufacturer price per vial		
Vial size	100 mg	500 mg
Current ex-manufacturer price	$452.72	$2,263.57
Rituximab IV dose (375 mg/m^2 X [redacted] m^2 BSA)	[redacted] mg [redacted]	
Ex-manufacturer price for [redacted] mg IV rituximab	$[redacted]	
Application of relevant fees and mark-ups	Public hospital use	Private hospital use
IV rituximab price + fees & mark-ups	$[redacted] = $[redacted] + $102.12	$[redacted] = $[redacted] + $139.14 + $40.00
Rituximab price for SC formulation (1400mg)	$[redacted]	$[redacted]

Note: Rituximab SC CMA.xlsx
Source: page 12 of the November 2014 PBAC submission

6.21 In the Pre-PBAC response, (p1) the sponsor stated, the November 2014 rituximab SC submission applied section 100 pricing only and that in this submission an additional General Schedule proposed price calculation was presented, consistent with the advice received from the PBAC Secretariat following the November 2014 recommendation.

6.22 The PBAC noted that a larger BSA was used to calculate the price of rituximab SC for CLL compared to the BSA used to calculate the price of rituximab SC in the November 2014 non-Hodgkin's lymphoma submission, however, it recalled that the BSA used in the original recommended submission for rituximab for CLL submission from November 2010 ([redacted] m^2) was slightly larger than that used in the current submission ([redacted] m^2).

Estimated PBS usage & financial implications

6.23 The financial analysis presented in the submission assumed no incremental growth in the rituximab market following the availability for the SC formulation and is based on moderate uptake of the SC formulation.

6.24 The submission stated that the PBS listing of rituximab 1,600 mg SC would result in a small increase in overall net cost to the PBS. This would be driven by higher mark-ups, handling and dispensing fees applied to General Schedule listings (rituximab 1,600 mg SC), compared to Section 100 EFC listings (rituximab IV).

6.25 The minor submission estimated a net cost to the PBS of less than $10 million in year 5 of listing, with a total net cost to the PBS of less than $10 million over the first 5 years of listing. This is summarised in the table below.

Table 8. Overall net cost to Commonwealth Government Health budget of listing rituximab SC

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Overall net cost to the PBS	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]
Overall net cost to the RPBS	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]

Source: Worksheet 'Summary' (MABTHERA SC CLL Minor PBAC.xlsx)

6.26 The PBAC considered that the price of rituximab SC should be adjusted so that there is no net cost to Government, consistent with the submission's cost-minimisation claim.

For more detail on PBAC's view, see section 7 "PBAC outcome"

7 PBAC Outcome

7.1 The PBAC recommended the listing of rituximab solution for subcutaneous injection, on the basis that it should be available as a General Schedule listing and under special arrangements under Section 100 – Efficient Funding of Chemotherapy (Schedule 2 – related pharmaceutical benefits).

7.2 The PBAC's recommendation for listing was based on, among other matters, its assessment, as described above, that the cost-effectiveness of rituximab SC would be acceptable if it were cost-minimised against rituximab IV.

7.3 The PBAC was satisfied that rituximab SC (1,600 mg) is non-inferior in terms of safety and efficacy compared with rituximab IV formulation at a dose of 500 mg/m^2.

7.4 The PBAC considered that the inclusion in the restriction of the following wording: An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab, was appropriate.

7.5 The PBAC noted the flow-on restriction changes to rituximab IV for the treatment of CLL (4615X and 7259C).

7.6 The PBAC accepted rituximab IV 500 mg/m^2 as the appropriate comparator.

7.7 The PBAC considered the requested listings of rituximab SC for the treatment of CLL was supported by the trials presented in the submission.

7.8 The PBAC accepted the SAWYER trial demonstrated comparable efficacy between rituximab SC and rituximab IV.

7.9 The PBAC accepted the SAWYER trial demonstrated comparable safety between rituximab SC and rituximab IV.

7.10 The PBAC noted the estimated net cost to the PBS of listing rituximab SC for CLL and considered that, consistent with the submission's cost-minimisation claim, the price of rituximab SC should be adjusted so that there is no net cost to Government.

7.11 The PBAC advised that rituximab is not suitable for prescribing by nurse practitioners.

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

Outcome:
Recommended

8 Recommended listing

8.1 Add new item:

Name, Restriction, Manner of administration and form	Max. Qty (units)	№.of Rpts	Proprietary Name and Manufacturer	
RITUXIMAB Solution for subcutaneous injection 1,600 mg/13.4 mL	1	4	MabThera® SC	Roche Products Pty Ltd

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	☐ Dental ☒ Medical Practitioners ☐ Nurse practitioners ☐ Optometrists ☐ Midwives
Condition:	Chronic lymphocytic leukaemia (CLL)
Restriction Level / Method:	☐ Restricted benefit ☐ Authority Required - In Writing ☐ Authority Required - Telephone ☐ Authority Required – Emergency ☐ Authority Required - Electronic ☒ Streamlined
Clinical criteria:	The condition must be CD20 positive chronic lymphocytic leukaemia (CLL), AND The treatment must be in combination with chemotherapy.
Prescriber Instructions	An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab.
Administrative Advice	No increase in the maximum number of repeats may be authorised. This drug is not PBS-subsidised for use as monotherapy.

Name, Restriction, Manner of administration and form	Max. Qty (units)	№.of Rpts	Proprietary Name and Manufacturer	
RITUXIMAB Solution for subcutaneous injection 1,600 mg/13.4 mL	1	4	MabThera® SC	Roche Products Pty Ltd

Category / Program	Section 100 – Efficient funding of Chemotherapy (Schedule 2 – related pharmaceutical benefits)
Prescriber type:	☐Dental ☒Medical Practitioners ☐Nurse practitioners ☐Optometrists ☐Midwives
Condition:	Chronic lymphocytic leukaemia (CLL)
Restriction Level / Method:	☐Restricted benefit ☐Authority Required - In Writing ☐Authority Required - Telephone ☐Authority Required – Emergency ☐Authority Required - Electronic ☒Streamlined
Clinical criteria:	The condition must be CD20 positive chronic lymphocytic leukaemia (CLL), AND The treatment must be in combination with chemotherapy.
Prescriber Instructions	An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab.
Administrative Advice	No increase in the maximum number of repeats may be authorised. This drug is not PBS-subsidised for use as monotherapy.

Amend existing listing as follows:

Name, Restriction, Manner of administration and form	Max. Amt.	№.of Rpts	Proprietary Name and Manufacturer	
RITUXIMAB				
Injection 100 mg/10 mL injection, 2 x 10 mL vials 500 mg/50 mL injection, 50 mL vial	1,100 mg	5	MabThera®	Roche Products Pty Ltd

Category / Program	Section 100 – Efficient funding of Chemotherapy – Public Hospital Use
Prescriber type:	☐ Dental ☒ Medical Practitioners ☐ Nurse practitioners ☐ Optometrists ☐ Midwives
Condition:	Chronic lymphocytic leukaemia (CLL)
Restriction Level / Method:	☐ Restricted benefit ☐ Authority Required - In Writing ☐ Authority Required - Telephone ☐ Authority Required – Emergency ☐ Authority Required - Electronic ☒ Streamlined
Clinical criteria:	The condition must be CD20 positive chronic lymphocytic leukaemia (CLL), AND The treatment must be in combination with chemotherapy.
Prescriber Instructions	An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab.
Administrative Advice	No increase in the maximum number of repeats may be authorised. This drug is not PBS-subsidised for use as monotherapy.

Name, Restriction, Manner of administration and form	Max. Amt.	№.of Rpts	Proprietary Name and Manufacturer
RITUXIMAB Injection 100 mg/10 mL injection, 2 x 10 mL vials 500 mg/50 mL injection, 50 mL vial	1,100 mg	5	MabThera® Roche Products Pty Ltd

Category / Program	Section 100 – Efficient funding of Chemotherapy – Private Hospital Use
Prescriber type:	☐ Dental ☒ Medical Practitioners ☐ Nurse practitioners ☐ Optometrists ☐ Midwives
Condition:	Chronic lymphocytic leukaemia (CLL)
Restriction Level / Method:	☐ Restricted benefit ☐ Authority Required - In Writing ☐ Authority Required - Telephone ☐ Authority Required – Emergency ☐ Authority Required - Electronic ☒ Streamlined
Clinical criteria:	The condition must be CD20 positive chronic lymphocytic leukaemia (CLL), AND The treatment must be in combination with chemotherapy.
Prescriber Instructions	An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab.
Administrative Advice	No increase in the maximum number of repeats may be authorised. This drug is not PBS-subsidised for use as monotherapy.

9 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.

10 Sponsor's Comment

The sponsor had no comment.