

## 5.21 RITUXIMAB

**1,400 mg/11.7 mL; solution for subcutaneous injection;  
Mabthera<sup>®</sup> SC; Roche Products Pty Ltd.**

### 1 Purpose of Application

- 1.1 The minor submission seeks the PBS listing of a new formulation of rituximab, suitable for subcutaneous (SC) administration, for patients with non-Hodgkin's lymphoma (NHL).

### 2 Requested listing

- 2.1 The submission seeks the same PBS listings for rituximab SC injection as that of rituximab IV infusion:
- 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, State 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.
- 2.2 The submission states that the sponsor will seek the same PBS listing of rituximab SC injection in maintenance setting as that of rituximab IV infusion if rituximab IV infusion is PBS listed for maintenance therapy.
- 2.3 The submission states that the highest risk of experiencing an infusion-related reaction with rituximab is during the first dose; thus, before starting rituximab SC, all patients must always receive beforehand, a full dose of rituximab by IV infusion. If patients were not able to receive one full rituximab IV infusion, they should continue subsequent cycles with IV rituximab until a full IV dose is successfully administered.
- 2.4 The requested basis for listing is a cost minimisation analysis of rituximab SC compared with rituximab IV in patients with previously untreated follicular lymphoma.

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

### 3 Background

- 3.1 Rituximab SC was TGA registered on 26 May 2014 for the following indications:
- CD20 positive, previously untreated, Stage III/IV follicular, B-cell non-Hodgkin's lymphoma;
  - CD20 positive, relapsed or refractory low grade or follicular, B-cell non-Hodgkin's lymphoma;
  - CD20 positive, diffuse large B-cell non-Hodgkin's lymphoma, in combination with chemotherapy.

3.2 Rituximab SC has not previously been considered by PBAC.

#### **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 PBAC noted 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 nominates IV rituximab as the comparator for SC rituximab.

*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, SABRINA, comparing rituximab SC to rituximab IV in patients with previously untreated follicular lymphoma. This was a two-stage open-label randomised trial.

- Stage 1 objective: to show the pharmacokinetic profile of SC rituximab was non-inferior to IV rituximab;
- Stage 2 objective: pooled results from Stages 1 and 2 to show comparable efficacy and safety between the SC and IV rituximab formulations.

6.4 Details of the SABRINA trial, as provided in the submission, are presented in the table below.

**Trials and associated reports presented in the submission**

Trial ID	Protocol title/ Publication title	Publication citation
<b>Direct randomised trials</b>		
SABRINA	<p>Davies A, Merli F, et al. Pharmacokinetics and safety of subcutaneous rituximab in follicular lymphoma (SABRINA): stage 1 analysis of a randomised phase 3 study.</p> <p>CSR BO22334 SABRINA - Stage 1 Synopsis. A two-stage phase III, international, multicenter, randomized, controlled, open-label study to investigate the pharmacokinetics, efficacy and safety of rituximab SC in combination with CHOP or CVP versus rituximab IV in combination with CHOP or CVP in patients with previously untreated follicular lymphoma followed by maintenance treatment with either rituximab SC or rituximab IV.</p> <p>CSR BO22334 SABRINA - Stage 2 Synopsis. A two-stage phase III, international, multi-center, randomized, controlled, open-label study to investigate the pharmacokinetics, efficacy and safety of rituximab SC in combination with CHOP or CVP versus rituximab IV in combination with CHOP or CVP in patients with previously untreated follicular lymphoma followed by maintenance treatment with either rituximab SC or rituximab IV.</p>	<p><i>The Lancet Oncology.</i> 2014;15(3):343-52.</p> <p>Report No.1047896. October. 2012:18-32.</p> <p>Report No. 1058994. June. 2014.</p>

Source: Page 13 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.
- 6.6 Overall response rate was used as the primary outcome for the efficacy study.

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

**Comparative effectiveness**

- 6.7 Results for the geometric mean ratio of trough serum concentrations between rituximab SC fixed dose 1,400 mg and rituximab IV 375 mg/m<sup>2</sup> are shown in the table below.

**Summary of Ctrough at Cycle 7 – SABRINA (ITT)**

PK Parameter	Rituximab IV			Rituximab SC			Geometric Mean Ratio <sup>a</sup> [90% CI]
	n	Geometric Mean	CV (%) <sup>b</sup>	n	Geometric Mean	CV (%) <sup>b</sup>	
Ctrough (mcg/ml)							
Stage 1	48	83.1	■	54	134.6	■	1.62 [1.36; 1.94]
Stage 2	■	■	■	■	■	■	■
Pooled analysis	■	■	■	■	■	■	■

Source: page14 of the submission

PK = pharmacokinetic; IV = intravenous; SC = subcutaneous; CI = confidence interval; CV = coefficient of variation  
 a Geometric mean ratio adjusted for tumour load at baseline.

b CV calculated on the original scale

6.8 The submission states that the primary outcome measure of the ratio of trough serum concentrations of the two rituximab formulations obtained at Cycle 7 (C<sub>trough</sub> SC/C<sub>trough</sub> IV) shows that the lower limit of the two-sided 90% CI, i.e. 1.36, was above the pre-specified non-inferiority margin of 0.8; therefore non-inferiority for the primary PK endpoint was demonstrated. Variability between the PK profiles of substances administered via different routes of administration is to be expected given differences in absorption and the sponsor has therefore not attempted to establish bioequivalence between IV and SC administration according to conventional PK criteria (AUC, C<sub>max</sub>, etc).

6.9 Results for the efficacy study are shown in the table below.

**Overall efficacy at the end of induction (ITT Population) – SABRINA pooled analysis Stage 1 and 2 (31 October 2013)**

	Number of patients (%)		
	Rituximab IV + Chemo (N=██)	Rituximab SC + Chemo (N=██)	
Responders <sup>§</sup>	██████████	██████████	
Non-Responders	██████████	██████████	
95% CI for Response Rates*	██████████	██████████	
Difference in Response Rates			██████████
95% CI for Difference in Response Rates#			██████████
p-Value (Chi-squared Test)			██████████
Odds Ratio			██████████
95% CI for Odds Ratio			██████████
Complete Response (CR and CRu)	██████████	██████████	
95% CI for CR and CRu Rates*	██████████	██████████	
Difference in CR and CRu Rates			██████████
95% CI for Difference in CR and CRu Rates#			██████████
p-Value (Chi-squared Test)			██████████
Odds Ratio			██████████
95% CI for Odds Ratio			██████████
Partial Response (PR)	██████████	██████████	
95% CI for PR Rates*	██████████	██████████	
Difference in PR Rates			██████████
95% CI for Difference in PR Rates#			██████████
p-Value (Chi-squared Test)			██████████
Odds Ratio			██████████
95% CI for Odds Ratio			██████████

Source: page 17 of the submission

Notes: Response: End of Induction-Derived (RSPEIND)

CR: complete response; CRu: complete response unconfirmed; PR: partial response

§ Patients with end of induction treatment response of CR, CRu or PR

\* 95% CI for one sample binomial using Pearson-Clopper

# Approximate 95% CI for difference of two rates using Hauck-Anderson method

- 6.10 The submission states the pooled efficacy results show that ORR (CR/CRu and PR) at the end of induction was comparable for the rituximab SC and IV arms; thereby demonstrating comparable efficacy results for both the SC and IV rituximab formulations.
- 6.11 As this was a minor submission, the results above have not been independently evaluated.

*For more detail on PBAC’s view, see section 7 “PBAC outcome”*

### Comparative harms

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

**Overview of AEs, deaths and withdrawals (Safety Analysis Population) - SABRINA pooled analysis Stage 1 and 2 (31 October 2013)**

Adverse events	Number of patients (%)	
	Rituximab IV + Chemo (N=██)	Rituximab SC + Chemo (N=██)
Total Patients with at least one AE	██	██
Total Number of AEs	██	██
Deaths #	██	██
Study withdrawals due to an AE #	██	██
Patients with at least one AE leading to death	██	██
Serious AE	██	██
Serious AE leading to dose withdrawal from treatment	██	██
Serious AE leading to dose modification/interruption	██	██
Treatment-related serious AE	██	██
AE leading to withdrawal from treatment	██	██
AE leading to dose modification/interruption	██	██
Treatment-related AE	██	██
Treatment-related AE leading to withdrawal from treatment	██	██
Treatment-related AE leading to dose modification/interruption	██	██
Severe AE	██	██

Source: page 18 of the submission

Multiple occurrences of the same AE in one individual counted only once

- 6.13 The PBAC noted that rituximab SC appears to have more treatment-related AEs compared to rituximab IV. However, the PBAC considered in general, rituximab SC is non-inferior in terms of safety compared with rituximab IV.

For more detail on PBAC’s view, see section 7 “PBAC outcome”

**Clinical claim**

- 6.14 The submission claimed non-inferior comparative effectiveness and non-inferior comparative safety of rituximab SC (fixed dose of 1,400 mg) compared with rituximab IV formulation (dosed at 375mg/m<sup>2</sup>).
- 6.15 The PBAC considered that the claim of non-inferior comparative effectiveness is reasonable.
- 6.16 The PBAC considered that the claim of non-inferior comparative safety is reasonable.

**Economic analysis**

- 6.17 The minor submission presented the following cost minimisation analysis.

**Rituximab IV and SC: Cost minimisation analysis**

Rituximab ex-manufacturer price per vial		
Vial size	██████	██████
Current ex-manufacturer price	██████	██████
Rituximab IV dose (375 mg/m <sup>2</sup> X 1.8m <sup>2</sup> BSA)	██	
Ex-manufacturer price for 680mg IV rituximab	██	
Application of relevant fees and mark-ups	Public hospital use	Private hospital use
IV rituximab price + fees & mark-ups	████████████████████	██
Rituximab price for SC formulation (1400mg)	██████	██████

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

- 6.18 The calculations are based on:
  - Current PBS prices for IV rituximab vials (100mg and 500mg);
  - The mean 1.8 m<sup>2</sup> body surface area (BSA) derived from a projected sample of 3,604 Australian patients who were treated for NHL from the Tandem Cancer Audit Program;
  - Dose equivalency between rituximab SC 1,400 mg and rituximab IV 375 mg/m<sup>2</sup>;
  - Application of the appropriate public and private hospital fees and mark-ups as per the efficient funding of chemotherapy drugs requirements.
- 6.19 The PBAC noted that a ██████ lower price of rituximab IV being effective on 1 December 2014 will impact the cost minimisation calculations.

For more detail on PBAC’s view, see section 7 “PBAC outcome”

## Estimated PBS usage & financial implications

- 6.20 The minor submission estimates a net saving to the PBS and MBS, due to the collection of two patient co-payments for the treatment regimen of IV rituximab followed by SC rituximab and no MBS item code available for the administration of rituximab SC. This is summarised in the table below.

**Overall net cost (savings) to Commonwealth Government Health budget of listing rituximab SC**

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Overall net saving to the PBS	████████	████████	████████	████████	████████	████████
Overall net saving to the RPBS	████████	████████	████████	████████	████████	████████
Overall net cost to Medicare Australia	████	████	████	████	████	████
Overall net savings for MBS	████████	████████	████████	████████	████████	████████
<b>Overall Net savings to Commonwealth Government Health Budget of listing Drug</b>	████████	████████	████████	████████	████████	████████

Source: page 20 of the submission

The redacted table shows that the estimated net savings to the Commonwealth is less than \$10 million per year.

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

## 7 PBAC Outcome

- 7.1 The PBAC recommended the listing of rituximab SC, on the basis that rituximab SC formulation is non-inferior in terms of efficacy and safety compared with rituximab IV formulation.
- 7.2 The PBAC noted the TGA accepted that the exposure of rituximab SC is non-inferior compared with body surface area adjusted IV therapy and that the clinical trial (SABRINA) data are consistent with equivalence in response and safety outcomes. The PBAC therefore accepted the equi-effective doses are rituximab SC 1,400 mg and rituximab IV 375 mg/m<sup>2</sup>.
- 7.3 The PBAC considered the requested listings of rituximab SC for the treatment of all types of CD20 positive B- cell Non-Hodgkin's Lymphoma are supported by the trials presented in the submission.
- 7.4 The PBAC noted the maximum quantity of rituximab SC requested is 1,400 mg, and the number of repeats is one less than that of rituximab IV, as the first dose is always by IV injection for safety reasons. The PBAC considered the maximum quantity and number of repeats of rituximab SC are appropriate.

- 7.5 The PBAC considered for safety reasons, including the wording “First dose of rituximab must be administrated intravenously using rituximab intravenous injection” in the PBS restriction is appropriate.
- 7.6 The PBAC accepted that rituximab SC offers a convenient alternative to the IV formulation.
- 7.7 The PBAC accepted rituximab IV as the appropriate comparator.
- 7.8 The PBAC accepted rituximab SC is non-inferior in efficacy and safety compared with rituximab IV.
- 7.9 The PBAC considered the cost minimisation against rituximab IV formulation is appropriate noting that the analysis is based simply on the price of the drug.
- 7.10 The PBAC noted the estimate net saving is due to the collection of two patient co-payments and reduced MBS billings. The PBAC considered the estimate of the overall net savings may not be accurate as some patients who receive rituximab IV infusion may not switch to rituximab SC, especially patients receiving both IV rituximab and IV chemotherapy at the same consultation.
- 7.11 The PBAC advised that under Section 101 (3BA) of the *National Health Act 1953* rituximab SC should be treated as interchangeable on an individual patient basis with rituximab IV.
- 7.12 The PBAC advised that rituximab is not suitable for prescribing by nurse practitioners.
- 7.13 The PBAC recommended that the Safety Net 20 Day Rule should not apply.
- 7.14 The PBAC noted that this submission is not eligible for an Independent Review.

**Outcome:**

Recommended

**8 Recommended listing**

8.1 Add new item:

Induction for previously untreated diffuse large B-cell non-Hodgkin’s lymphoma:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer
RITUXIMAB Solution for subcutaneous injection 1,400 MG/11.7ML	1,400 mg	6	Mabthera®SC Roche Products Pty Limited

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<b>Category / Program</b>	GENERAL SCHEDULE S100 – Chemotherapy Scheme – CPAP Public Hospital (CT)
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>Episodicity:</b>	Previously untreated
<b>Severity:</b>	
<b>Condition:</b>	CD20 positive diffuse large B-cell Non-Hodgkin's lymphoma
<b>Treatment phase:</b>	Induction treatment
<b>Restriction Level / Method:</b>	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required – Electronic OR <input checked="" type="checkbox"/> Streamlined
<b>Clinical criteria:</b>	The treatment must be in combination with chemotherapy, AND The condition must be previously untreated, AND The condition must be symptomatic, AND The treatment must be for induction treatment purposes only, AND Patient must not receive more than 8 doses of rituximab in total, including intravenous and subcutaneous injections, and no more than 7 doses of subcutaneous rituximab under this restriction.
<b>Prescriber Instruction</b>	An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab with no more than 8 doses in total.
<b>Administrative Advice</b>	A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.
<b>Administrative Advice</b>	No increase in the maximum number of repeats may be authorised.

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**Induction for previously untreated follicular non-Hodgkin's lymphoma:**

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
RITUXIMAB Solution for subcutaneous injection 1,400 MG/11.7ML	1,400 mg	6	Mabthera®SC	Roche Products Pty Limited

<b>Category / Program</b>	GENERAL SCHEDULE S100 – Chemotherapy Scheme – CPAP Public Hospital (CT)
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>Episodicity:</b>	Previously untreated
<b>Severity:</b>	Stage III or IV
<b>Condition:</b>	CD20 positive follicular B-cell Non-Hodgkin's lymphoma
<b>Treatment phase:</b>	Induction treatment
<b>Restriction Level / Method:</b>	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required – Electronic OR <input checked="" type="checkbox"/> Streamlined
<b>Clinical criteria:</b>	The treatment must be in combination with chemotherapy, AND The condition must be previously untreated, AND The condition must be symptomatic, AND The treatment must be for induction treatment purposes only, AND Patient must not receive more than 8 doses of rituximab in total, including intravenous and subcutaneous injections, and no more than 7 doses of subcutaneous rituximab under this restriction.
<b>Prescriber Instruction</b>	An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab with no more than 8 doses in total.
<b>Administrative Advice</b>	A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.
<b>Administrative Advice</b>	No increase in the maximum number of repeats may be authorised.

**Induction and re-induction for relapsed/refractory low grade B-cell non-Hodgkin's lymphoma:**

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer
Rituximab Solution for subcutaneous injection 1,400 mg/11.7mL	1,400 mg	2	Mabthera®SC Roche Products Pty Limited

<b>Category / Program</b>	GENERAL SCHEDULE S100 – Chemotherapy Scheme – CPAP Public Hospital (CT)
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>Episodicity:</b>	Relapsed or refractory
<b>Condition:</b>	Low-grade B-cell non-Hodgkin's lymphoma
<b>Treatment phase:</b>	Re-induction treatment
<b>Restriction Level / Method:</b>	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required – Electronic OR <input checked="" type="checkbox"/> Streamlined
<b>Clinical criteria:</b>	The treatment must be for re-induction treatment purposes only, AND The condition must have relapsed or be refractory to treatment, AND Patient must not receive more than 4 doses of rituximab in total, including intravenous and subcutaneous injections, and no more than 3 doses of subcutaneous rituximab under this restriction.
<b>Prescriber Instruction</b>	An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab with no more than 4 doses in total.
<b>Administrative Advice</b>	No increase in the maximum number of repeats may be authorised.

**Induction and re-induction for relapsed/refractory follicular B-cell non-Hodgkin's lymphoma:**

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer
Rituximab Solution for subcutaneous injection 1,400 mg/11.7mL	1,400 mg	2	Mabthera®SC Roche Products Pty Limited

<b>Category / Program</b>	GENERAL SCHEDULE S100 – Chemotherapy Scheme – CPAP Public Hospital (CT)
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>Episodicity:</b>	Relapsed or refractory
<b>Condition:</b>	Follicular B-cell non-Hodgkin's lymphoma
<b>Treatment phase:</b>	Re-induction treatment
<b>Restriction Level / Method:</b>	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required – Electronic OR <input checked="" type="checkbox"/> Streamlined
<b>Clinical criteria:</b>	The treatment must be for re-induction treatment purposes only, AND The condition must have relapsed or be refractory to treatment, AND Patient must not receive more than 4 doses of rituximab in total, including intravenous and subcutaneous injections, and no more than 3 doses of subcutaneous rituximab under this restriction.
<b>Prescriber Instruction</b>	An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab with no more than 4 doses in total.
<b>Administrative Advice</b>	No increase in the maximum number of repeats may be authorised.

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**Maintenance therapy for previously untreated follicular lymphoma:**

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
RITUXIMAB Solution for subcutaneous injection 1,400 MG/11.7ML	1,400 mg	11	Mabthera®SC	Roche Products Pty Limited

<b>Category / Program</b>	GENERAL SCHEDULE S100 – Chemotherapy Scheme – CPAP Public Hospital (CT)
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>Episodicity:</b>	
<b>Severity:</b>	Stage III or IV
<b>Condition:</b>	CD20 positive follicular B-cell Non-Hodgkin's lymphoma
<b>Treatment phase:</b>	Maintenance therapy
<b>Restriction Level / Method:</b>	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required – Electronic OR <input checked="" type="checkbox"/> Streamlined
<b>Clinical criteria:</b>	Patient must have demonstrated a partial or complete response to the induction phase of treatment for previously untreated follicular B-cell Non-Hodgkin's lymphoma, received immediately prior to this current Authority application, AND The treatment must be for maintenance therapy, AND Patient must not receive more than 12 doses or 2 years duration of treatment, whichever comes first, under this restriction.
<b>Administrative Advice</b>	A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.
<b>Administrative Advice</b>	No increase in the maximum number of repeats may be authorised.
<b>Administrative Advice</b>	Special pricing arrangements apply

**Maintenance therapy for relapsed/refractory follicular disease:**

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer
RITUXIMAB Solution for subcutaneous injection 1,400 MG/11.7ML	1,400 mg	7	Mabthera®SC Roche Products Pty Limited

<b>Category / Program</b>	GENERAL SCHEDULE S100 – Chemotherapy Scheme – CPAP Public Hospital (CT)
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>Episodicity:</b>	Relapsed or refractory
<b>Severity:</b>	Stage III or IV
<b>Condition:</b>	CD20 positive follicular B-cell non-Hodgkin's lymphoma
<b>Treatment phase:</b>	Maintenance therapy
<b>Restriction Level / Method:</b>	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required – Electronic OR <input checked="" type="checkbox"/> Streamlined
<b>Clinical criteria:</b>	The treatment must be for maintenance therapy, AND Patient must have demonstrated a partial or complete response to re-induction treatment received immediately prior to this current Authority application, AND Patient must not receive more than 8 cycles or 2 years duration of treatment, whichever comes first, under this restriction.
<b>Administrative Advice</b>	No increase in the maximum number of repeats may be authorised.
<b>Administrative Advice</b>	Special pricing arrangements apply

**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.