

## 9.01 Biologics for the treatment of chronic plaque psoriasis: Cost-effectiveness review

### 1 Purpose of item

- 1.1 In April 2018, the PBAC requested a cost-effectiveness review (CER) of biologics for severe chronic plaque psoriasis (CPP) under the current PBS restrictions, and to consider the additional PBS population that meet the criteria of a baseline Psoriasis Area and Severity Index (PASI)  $\geq 12$  to  $\leq 15$  AND/OR a Dermatology Life Quality Index (DLQI)  $> 10$ . The purpose of this item was for the PBAC to consider the ‘Biologics for the treatment of chronic plaque psoriasis (CPP): cost-effectiveness review’ report. The PBAC also considered the DUSC and ESC advice from June 2020, Sponsor Pre-PBAC responses and one stakeholder response.

### 2 Background

- 2.1 Biologics (also referred to as biologic disease modifying antirheumatic drugs (bDMARDs)) are a group of anti-inflammatory and immune-suppressing agents that are used to treat rheumatoid arthritis and other autoimmune diseases including Crohn’s disease, ankylosing spondylitis, psoriatic arthritis and severe CPP. PBS-listed biologics for CPP accounted for \$161.9M (published) of PBS expenditure in financial year 2018-19.<sup>1</sup> There are currently nine PBS-listed biologics for severe CPP, the most recent being the listing of risankizumab in December 2019.
- 2.2 A post-market review (PMR) of the use of biologics in the treatment of severe CPP (the ‘Review’) was recommended by the PBAC in December 2015 and approved by the Minister on 7 April 2016.
- 2.3 The final Terms of Reference for the Review were:
- 1) Review current clinical guidelines for the treatment of severe chronic plaque psoriasis and compare to the Pharmaceutical Benefits Scheme (PBS) restrictions for use of biologics in this indication.
  - 2) Review and evaluate recent clinical evidence on the efficacy and safety of biologics used in the treatment of severe chronic plaque psoriasis and compare to the evidence considered by the Pharmaceutical Benefits Advisory Committee (PBAC) in previous Sponsor submissions.
  - 3) Review the utilisation of PBS biologics for the treatment of chronic plaque psoriasis including time on treatment and discontinuation from treatment, and compare this with that observed in the clinical trial evidence considered by the PBAC.

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<sup>1</sup> Based on publicly available PBS data from the Services Australia website

- 4) Subject to the findings from Terms of Reference 1, 2 and 3, review the cost-effectiveness of biologics for severe chronic plaque psoriasis.
- 2.4 The draft Review report, including the PBAC Sub-Committee advice and stakeholder comments, was provided to the PBAC for consideration in April 2018. Based on the findings from Terms of Reference 1, 2 and 3 the PBAC recommended a change to the PBS restrictions for all biologics listed for CPP. This change reduced the number of treatments a patient must trial (from three to two) before being eligible for PBS-subsidised biologic therapy. The recommended restriction change was implemented on 1 May 2019.
- 2.5 The PBAC also requested a CER of biologics under the current PBS restrictions, and to consider the PMR proposed additional PBS population that meet the criteria of a baseline PASI  $\geq 12$  to  $\leq 15$  AND/OR a DLQI  $> 10$ .
- 2.6 In October 2018, the Department contracted [REDACTED] to undertake the CER of Biologics. The overall purpose of the CER was to establish the cost-effectiveness of all PBS-listed biologics for the treatment of CPP in patients who have failed to achieve an adequate response to at least two of the following therapies: phototherapy, methotrexate, ciclosporin and/or acitretin for at least 6 weeks. Currently, PBS-subsidised biologics for CPP are restricted to use in patients with a baseline PASI  $> 15$  who have failed at least two of these therapies.
- 2.7 The following medicines were considered in the CER of PBS-listed biologics used in the treatment of CPP:
- Etanercept;
  - Infliximab;
  - Adalimumab;
  - Ustekinumab;
  - Secukinumab;
  - Ixekizumab;
  - Guselkumab; and
  - Tildrakizumab.
- 2.8 The CER Report was provided to Sponsors for consultation on two occasions for a minimum of two weeks and Sponsors were invited to submit Pre-Sub-Committee Responses (PSCRs) and pre-PBAC responses. Members of the Reference Group for the PMR of the use of biologics for severe chronic plaque psoriasis were also given the opportunity to provide feedback on the CER Report prior to PBAC consideration.

### **3 Evidence evaluation**

#### ***Population and setting***

- 3.1 For the purpose of the CER, a reference biologic (secukinumab) was nominated as [REDACTED]

most biologics have been cost-minimised to each other (over 104 weeks of treatment), such that non-inferiority has been accepted. Nonetheless, all other biologics were tested in separate sensitivity analyses.

- 3.2 Sponsors were invited to provide data to inform the effectiveness of the biologics in each of the following subgroups:
- Severe CPP with PASI > 15;
  - Moderate-severe CPP with PASI ≥ 12 to ≤ 15;
  - Moderate-severe CPP with PASI ≥ 12 to ≤ 15 AND DLQI > 10; and
  - Moderate-severe CPP with PASI ≥ 12 to ≤ 15 OR DLQI > 10.
- 3.3 Analyses of the trial data and tests for interaction were conducted to determine whether disease severity, however defined, was a treatment effect modifier. The majority of analyses indicated no treatment effect modification based on disease severity and there was no consistent signal amongst subgroups where treatment effect modification was potentially indicated. Therefore, whole trial data was used to inform efficacy in the initiation period for all subgroups.
- 3.4 The derivation of the cost-effectiveness of biologics in the subgroups including DLQI were considered uninformative because:
- There were very few patients with DLQI > 10 AND PASI ≥ 12 to ≤ 15 in the study populations; and
  - The DLQI > 10 subgroup did not represent a mutually exclusive group to those for whom biologics are already PBS-listed (PASI > 15).

### ***Model overview and assumptions***

- 3.5 A 'Base case' for the current review was established for patients with a baseline PASI of ≥ 12 to ≤ 15 with regards to utilities and health state costs using inputs from secukinumab with regards to drug costs and efficacy. The incremental cost effectiveness ratio (ICER) from the Base case model is referred to as the 'Base case ICER.' In comparison, the ICER for patients with a baseline PASI of > 15 was referred to as the 'Existing ICER.'
- 3.6 A stepped economic evaluation using secukinumab as the reference biologic was conducted. This approach allowed the gradual introduction of differences (and uncertainty) between the baseline PASI ≥ 12 to ≤ 15 and the PASI > 15 subgroups, as part of the proposed expansion of the PBS listing for CPP, and illustrates the impact of each input incrementally. The steps of the economic evaluation are described in **Table 1**.

**Table 1 Outline of stepped economic evaluation**

Step	Time horizon	Outcome	Differences in model inputs between baseline PASI $\geq 12$ to $\leq 15$ and PASI $> 15$
Step 1 Trial based	12 weeks	PASI 75 responder	No difference
Step 2 Extrapolate to 5 years	5 years	PASI 75 responder/year	No difference
Step 3 Convert to QALY	5 years	QALY	No difference
Step 4 Include hospitalisation costs for no treatment/non-responder	5 years	QALY	<u>Existing ICER</u> No difference
Step 5 Assume different baseline utility	5 years	QALY	Higher non-responder utility
Step 6 Assume lower hospitalisation costs for no treatment/non-responder	5 years	QALY	<u>Base case ICER</u> Higher non-responder utility, lower no treatment/non-responder health state costs

PASI = Psoriasis Area and Severity Index; PASI 75 = 75% improvement on baseline PASI; QALY = quality adjusted life year  
Source: compiled during the evaluation

- 3.7 Consistent with the previous (re)submissions considered by the PBAC for severe CPP, a Markov model was presented. In the Base case, only one line of therapy was considered for both the intervention and comparator (i.e. secukinumab versus placebo). However, the model was structured to allow up to three consecutive lines of therapy for both the intervention and the comparator, and this was tested in sensitivity analyses. The efficacy of the second and third-line therapies were assumed to be the same as the biologic used as first-line therapy.
- 3.8 Patients were initially assumed to be non-responders to first-line therapies and were randomised to receive either secukinumab or placebo. At the end of the initiation period (16 weeks), a proportion of patients are considered to achieve a 75% improvement in baseline PASI (PASI 75 responders) which was informed by the results of the pivotal clinical trials using whole trial population data in the Base case. After the initiation period, patients who were considered to be PASI 75 responders could maintain response, or lose response and move into the non-responder state where it was assumed that they would cease treatment, each cycle. The cycle length can vary, but in the Base case it was assumed to be equal to the maintenance-dosing interval of secukinumab (4 weeks). Maintenance of response was informed by the proportion of patients remaining on PBS-listed treatment based on PBS utilisation data. The non-responder/no treatment state was considered an absorbing state, and patients were assumed to never achieve a PASI 75 response again for the remainder of the model.
- 3.9 Costs and effects were discounted at an annual rate of 5%, and were accrued at the beginning of each cycle with no half-cycle correction applied. The utilities applied in the model (to inform both the Base case and Existing ICERs) were taken from a patient preference study of 87 participants with psoriasis (Zug et. al. 1995) and are summarised in **Table 2**. A literature review was conducted to identify alternative utility

sources and the utility values from Geale et. al. (2017),<sup>2</sup> a study of 2,674 patients on the Swedish psoriasis register, were tested in sensitivity analyses. In addition, alternative utilities were provided by a Sponsor in their PSCR and pre-PBAC responses.

**Table 2** Utilities applied in the economic model

Health state	PASI >15	PASI ≥12 to ≤15
PASI 75 responder	0.89	0.89
PASI 75 non-responder	0.59	0.79

Source: Zug et. al. 1995

3.10 Costs for biologics were based on the effective (and indication specific) prices. Because of the different administration schedules for each therapy, an average weekly cost for each was calculated and then multiplied by the nominated cycle length (4 weeks in the Base case) to estimate the cost of maintenance therapy per cycle. The only cost applied to responders (PASI > 75% response) were drug costs. For non-responders differential hospitalisation costs were applied to reflect less severe disease in the PASI ≥ 12 to ≤ 15 subgroup versus the PASI > 15 subgroup.

### ***Main findings of the economic analysis***

3.11 The results of the stepped economic evaluation of secukinumab versus placebo are presented in **Table 3**.

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<sup>2</sup> Geale, K., Henriksson, M. & Schmitt-Egenolf, M. How is disease severity associated with quality of life in psoriasis patients? Evidence from a longitudinal population-based study in Sweden. *Health Qual Life Outcomes* 15, 151 (2017).

**Table 3 Results of stepped economic evaluation of secukinumab vs placebo**

Data	Costs			Health outcomes			ICER
	Secukinumab	Placebo	Increment	Secukinumab	Placebo	Increment	
Trial based (12 weeks, PASI 75 responder)	\$ [REDACTED]	\$0	\$ [REDACTED]	0.796	0.43	0.753	\$ [REDACTED]
Extrapolate to 5 years, PASI 75 responder (years)	\$ [REDACTED]	\$0	\$ [REDACTED]	2.659	0.203	2.456	\$ [REDACTED]
Extrapolate to 5 years, QALYs using baseline PASI >15 utilities (0.89/0.59 responder/non-responder)	\$ [REDACTED]	\$0	\$ [REDACTED]	3.423	2.745	0.678	\$ [REDACTED]
<b>Existing ICER</b>							
Extrapolate to 5 years, QALYs using baseline PASI >15 utilities (0.89/0.59 responder/non-responder), include hospitalisation (major)	\$ [REDACTED]	\$1,543	\$ [REDACTED]	3.423	2.745	0.678	\$ [REDACTED]
Extrapolate to 5 years, QALYs using baseline PASI ≥12 to ≤15 utilities (0.89/0.79 responder/non-responder), include hospitalisation (major)	\$ [REDACTED]	\$1,543	\$ [REDACTED]	3.846	3.621	0.226	\$ [REDACTED]
<b>Base case ICER (PASI ≥12 to ≤15)</b>							
Extrapolate to 5 years, QALYs using baseline PASI ≥12 to ≤15 utilities (0.89/0.79 responder/non-responder) and lower non-responder hospitalisation cost (minor)	\$ [REDACTED]	\$447	\$ [REDACTED]	3.846	3.621	0.226	\$ [REDACTED]

Source: derived from the modelled economic evaluation

- 3.12 The Existing ICER, for secukinumab versus placebo in patients with a baseline PASI > 15, was estimated to be \$15,000/QALY - \$45,000/QALY. The Base case ICER, in patients with a baseline PASI of ≥ 12 and ≤ 15, was \$105,000/QALY – \$200,000/QALY.
- 3.13 In order for the Base case ICER to match the Existing ICER, the indication specific dispensed price for maximum quantity (DPMQ) (2 × 150mg pens) of secukinumab for patients with baseline PASI ≥ 12 to ≤ 15 would need to be \$ [REDACTED], representing a [REDACTED]% reduction from the current indication specific price.
- 3.14 The ICER for both the Base case and Existing ICER are sensitive to the utility values used and the proportion of PASI 75 responders. The ICER was not sensitive to adding more lines of treatment, cycle length changes or placebo maintenance rates. The model was moderately sensitive to a change in time horizon, and while the current review adopts a 5 year time horizon, it may also be appropriate to consider a 2 year time horizon ('Base case' ICER \$105,000/QALY – \$200,000/QALY) given that biologics are currently listed on a cost-minimisation basis (of total cost) over 104 weeks (2 years).

**Estimated PBS usage & financial implications**

- 3.15 The CER was considered by the DUSC in June 2020.

3.16 The number of CPP patients with baseline PASI  $\geq 12$  to  $\leq 15$  estimated to use biologics is summarised in **Table 4**.

**Table 4 Estimated number of CPP patients with baseline PASI  $\geq 12$  to  $\leq 15$  treated with biologics**

	2020	2021	2022	2023	2024	2025
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Australian population	25,873,480	26,301,274	26,727,025	27,147,199	27,562,195	27,970,435
Psoriasis prevalence	646,837	657,532	668,176	678,680	689,055	699,261
CPP prevalence	511,001	519,450	527,859	536,157	544,353	552,416
CPP PASI $\geq 10$ to $\leq 15$	40,880	41,556	42,229	42,893	43,548	44,193
CPP PASI $\geq 12$ to $\leq 15$	17,170	17,454	17,736	18,015	18,290	18,561
Eligible for biologics	10,680	10,856	11,032	11,205	11,377	11,545
<b>Total patient uptake</b>	<b>4,405</b>	<b>4,750</b>	<b>5,240</b>	<b>5,883</b>	<b>6,542</b>	<b>6,638</b>
Initiating patients	4,405	1,710	1,439	1,626	1,709	1,248
Continuing patients	0	3,040	3,801	4,257	4,832	5,390

Source: derived during the evaluation

3.17 The uptake rate used in the Base case was the unweighted average of the assumed uptake rates applied in the ustekinumab 2009 and adalimumab 2013 submissions (i.e. 41%, 44%, 48%, 53%, 58%, and 58% from Years 1 to 6 respectively). The PBAC had previously noted that the patient estimates in the adalimumab submission were highly uncertain and were considerably lower than estimates revised during evaluation (paragraph 12.8 adalimumab PSD March 2013). The assumed uptake rates applied in the ustekinumab (2009) and adalimumab (2013) submissions were tested in sensitivity analyses.

3.18 The PBAC has previously noted that subsidised use of biologics outside PBS restrictions, i.e. in patients with less severe CPP, was a risk as determination of a PASI score is subjective (paragraph 12.9 adalimumab PSD March 2013). In addition, it is unclear how the uptake rate in those with less severe disease (PASI  $\geq 12$  to  $\leq 15$ ) will compare to the uptake rate in those with severe disease (PASI  $> 15$ ). Barriers to accessing biologics, including the requirement to see a dermatologist and acceptability of injection, may influence uptake rates in a subgroup with less severe disease.

3.19 In the Base case, it is assumed that secukinumab will be the only biologic used in the baseline PASI  $\geq 12$  to  $\leq 15$  subgroup. The estimated expenditure on secukinumab in CPP patients with baseline PASI  $\geq 12$  to  $\leq 15$  using effective prices and assuming a [REDACTED] % price reduction is presented in **Table 5**.

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**Table 5 Estimated expenditure on secukinumab in CPP patients with baseline PASI ≥ 12 to ≤ 15 using published and effective price and assuming █████% price reduction**

	2020	2021	2022	2023	2024	2025
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Total Scripts	30,837	51,485	59,487	66,722	74,785	78,809
Scripts PBS	30,775	51,382	59,368	66,588	74,636	78,652
Scripts RPBS	62	103	119	133	150	158
Cost of secukinumab (published)	\$44,949,706	\$75,046,716	\$86,710,729	\$97,257,141	\$109,010,601	\$114,876,132
Cost of secukinumab effective (CPP indication-specific)	\$████████	\$████████	\$████████	\$████████	\$████████	\$████████
Cost of secukinumab effective (indication-specific), █████% price reduction	\$████████	\$████████	\$████████	\$████████	\$████████	\$████████
Total co-payment PBS	\$920,493	\$1,536,828	\$1,775,687	\$1,991,660	\$2,232,351	\$2,352,467
Total co-payment RPBS	\$401	\$669	\$773	\$867	\$972	\$1,025
<b>Net cost to PBS/RPS (published)</b>	\$44,028,812	\$73,509,218	\$84,934,268	\$95,264,613	\$106,777,278	\$112,522,640
<b>Net cost to PBS/RPBS (effective)</b>	\$████████	\$████████	\$████████	\$████████	\$████████	\$████████
<b>Net cost to PBS/RPBS (effective, █████% price reduction)</b>	\$████████	\$████████	\$████████	\$████████	\$████████	\$████████
Total specialist costs	\$390,750	\$421,284	\$464,798	\$521,801	\$580,232	\$588,827
Net cost to government (inc specialist), published	\$44,419,562	\$73,930,502	\$85,399,066	\$95,786,414	\$107,357,511	\$113,111,467
Net cost to government (inc specialist), effective (indication-specific)	\$████████	\$████████	\$████████	\$████████	\$████████	\$████████
Net cost to government (inc specialist), effective (indication-specific), █████% discount	\$████████	\$████████	\$████████	\$████████	\$████████	\$████████

Source: derived during the evaluation

3.20 The redacted **Table 5** shows that in the Base case, using the epidemiological approach for CPP patients with baseline PASI ≥ 12 to ≤ 15 and assuming a █████% discount on the indication specific price, the estimated net cost to the PBS/RPBS in Year 6 would be \$10 – \$20 million per year.

3.21 The net cost to the PBS in the PASI > 15 population (total PBS market) is based on the current PBS market share (patient numbers currently treated) and the assumption that all patients will be treated with secukinumab. The number of scripts per patient was based on the same number of scripts estimated in the PASI ≥ 12 to ≤ 15 population for secukinumab; seven for initiating patients (first year) and thirteen per year for maintenance patients. This approach slightly overestimated the cost of the total PBS

market as it applied the secukinumab price to the whole market, which also included lower cost biologics such as etanercept and infliximab.

- 3.22 The estimated net cost to the PBS/RPBS for the total biologics market for CPP (PASI  $\geq$  12), based on the price of secukinumab, was estimated to be more than \$100 million in Year 6.
- 3.23 The wording of the proposed draft PBS restrictions for biologics for CPP were determined following consultation with Services Australia. All PBS item codes that refer to treatment initiation with a biologic (for whole body CPP) have been amended to require patients to have a baseline PASI of '12 or greater' from the current 'greater than 15.' No changes have been proposed to PBS restrictions for treatment initiation of patients with severe CPP of the face, hand or foot as this was outside the scope of the CER.
- 3.24 No changes have been proposed to the PBS restrictions for biologic treatment continuation for patients with whole body CPP as irrespective of a patient's baseline PASI score; they are still required to achieve a 75% PASI improvement to be eligible for continuation therapy with the same biologic. Although the structure of the PBS restrictions differ between biologics, the principle changes made are the same.
- 3.25 The proposed single restriction for the CPP population with baseline PASI of '12 or greater' would require a weighted price. The CER presented a weighted price for secukinumab based on the number of patients enrolled in clinical trials. It was estimated that █% █ of all patients enrolled in the clinical trials had a baseline PASI of  $\geq$  12 to  $\leq$  15 and █% have a baseline PASI  $>$  15.
- 3.26 The Department has consulted Services Australia regarding the capture of utilisation data in the PASI  $\geq$  12 to  $\leq$  15 population and the currently eligible PASI  $>$  15 population. Services Australia advised that baseline PASI scores, and PASI scores for patients responsive to treatment (following initiation of a biologic) can be captured in written authority applications and made accessible to the Department via data feed.

## **4 PBAC outcome**

- 4.1 The PBAC noted the Sponsor pre-PBAC responses and one stakeholder submission.
- 4.2 The PBAC recalled that in its April 2018 consideration of the PMR report for biologics in CPP, "the PBAC requested a CER to consider the additional PBS population's treated with biologics that meet the eligibility criteria of a baseline PASI of  $\geq$  12 to  $\leq$  15 and a DLQI  $>$  10. Where possible this analysis should also consider the inclusion of the 'OR DLQI  $>$  10' population in addition to those who meet the combined eligibility requirement of a baseline PASI  $\geq$  12 to  $\leq$  15 and DLQI  $>$ 10."
- 4.3 The PBAC agreed with Sponsors that the CER did not specifically address the population with a DLQI  $>$  10 separately to those with a PASI  $\geq$  12. The PBAC recalled that in its consideration of the PMR report for biologics in CPP, "the PBAC was uncertain that there was sufficient evidence to support the inclusion of DLQI in the

restriction criteria (7.01 April 2018 Minutes, paragraph 4.3.4).” The PBAC noted the evaluator comments that there were very few patients in the PASI  $\geq 12$  to  $\leq 15$  AND DLQI  $> 10$  subgroup in the clinical trial data and that the DLQI  $> 10$  subgroup did not represent a mutually exclusive group. The PBAC were concerned that there may be a small population with a DLQI  $> 10$  and a PASI  $< 12$  who remain ineligible for treatment.

- 4.4 The PBAC noted that secukinumab was nominated as the reference biologic because:
- The relative efficacy of secukinumab compared to placebo is close to the middle among all the biologics considered; and
  - Secukinumab has been listed on the PBS since September 2015 and there is a reasonable amount of utilisation data to inform maintenance rates in the Australian population currently treated with secukinumab.
- 4.5 The PBAC recalled that in July 2019, in the Committee’s consideration of risankizumab, it considered; “there was unlikely to be any clinically significant difference in long-term outcomes between any of the PBS-listed biologics available for use in CPP (paragraph 7.5, risankizumab PSD July 2019).” The PBAC noted that based on the Committee’s consideration of risankizumab, the ESC advised that the use of a reference biologic (secukinumab) was appropriate.
- 4.6 The PBAC noted that PBS utilisation data was used to inform maintenance rates in the model beyond the duration of the clinical trial data provided. The PBAC considered that there may be uncertainty in the maintenance rates accurately reflecting treatment failure, as patients may switch between biologics for reasons such as the method of administration (e.g. I.V. infusion versus subcutaneous injection) and a more convenient dosage regimen (e.g. once weekly injection versus 12 weekly injection).
- 4.7 The PBAC noted that the incremental cost effectiveness ratio (ICER) for the PASI  $> 15$  subgroup (the ‘Existing ICER’) was \$15,000/QALY - \$45,000/QALY and the ICER for the PASI  $\geq 12$  to  $\leq 15$  subgroup (the ‘Base case ICER’) was \$105,000/QALY – \$200,000/QALY. The PBAC noted that the CER stated that a price reduction of ██████% (from the current indication specific price for the PASI  $> 15$  subgroup) is required in the PASI  $\geq 12$  to  $\leq 15$  subgroup to maintain the same ICER across both populations.
- 4.8 The PBAC noted that while the ICER for secukinumab was used as the Base case ICER, sensitivity analyses were performed by the evaluator for other biologics for CPP. The PBAC noted that the ICER for secukinumab was ██████████ among biologics in the F1 formulary.
- 4.9 The PBAC agreed with the ESC advice that; “the model is highly sensitive to the utility values used and noted that this was driven by the incremental utility gain of 0.3 (0.89-0.59) per responder in the PASI  $> 15$  subgroup versus an incremental utility gain of 0.1 (0.89-0.79) per responder in the PASI  $\geq 12$  to  $\leq 15$  subgroup.”
- 4.10 The PBAC noted that the ESC and several Sponsors had raised concerns with using the utility values from Zug et. al. (1995) due to the study’s small sample size and because

it was now dated. The PBAC also noted the ESC advice that the utilities from Zug et al. have been presented in prior PBAC submissions and previously accepted by the PBAC. The PBAC considered that there is very little consistency in published utility values for CPP and noted that if the utility values provided by one Sponsor (in their pre-PBAC response) were applied to the current model, the Existing ICER would increase by █%. The PBAC considered that if alternative utilities were used this would alter the ICER for the PASI > 15 population previously accepted by the PBAC.

- 4.11 The PBAC noted that the CER assumed that in the Base case 5% of all patients who were non-responders would require one hospitalisation per year. The PBAC noted the ESC advice that “it would be more appropriate to assume an 11% hospitalisation rate in the Base case” as per the █. The PBAC noted that the CER tested an 11% hospitalisation rate in a sensitivity analysis that reduced the Base case ICER and the Existing ICER by █% and █% respectively and considered this change did not significantly impact the ICER.
- 4.12 The PBAC noted that the CER estimated that the costs of expanding access to biologics to those with a baseline PASI  $\geq 12$  to  $\leq 15$  (assuming a █% discount on the current indication specific price) would be \$10 – \$20 million per year in Year 6.
- 4.13 The PBAC noted advice from the DUSC that the estimates for the PASI > 15 PBS market nearly doubled in the number of initiating patients from 2020 to 2025. The DUSC advised that in a mature market, this growth in utilisation suggests leakage into another (less severe disease) population. The PBAC agreed with the DUSC that leakage into a less severe CPP population is the most likely reason behind the continued growth of this mature market.
- 4.14 The PBAC agreed with the DUSC advice that; “the estimates for the PASI  $\geq 12$  to  $\leq 15$  population were not robust and are likely an overestimate due to: lack of evidence to support the relative distribution of patients with PASI  $\geq 12$  relative to PASI  $\geq 10$ ; and uncertainty in the rate of uptake of biologics in the PASI  $\geq 12$  to  $\leq 15$  population.”
- 4.15 The PBAC did not recommend expanding the PBS restrictions for CPP to include patients with a baseline PASI score of  $\geq 12$  to  $\leq 15$ . The PBAC considered the ICER of \$105,000/QALY – \$200,000/QALY in the PASI  $\geq 12$  to  $\leq 15$  subgroup unacceptably high and uncertain. The PBAC considered that it was likely that a proportion of patients with a baseline PASI of < 15 were already being treated with PBS-subsidised biologics. In addition, the PBAC considered that the positive recommendation of apremilast (July 2020) for CPP, if progressed to PBS listing, will provide another treatment option for CPP patients presenting with a baseline PASI in the  $\geq 12$  to  $\leq 15$  range.
- 4.16 The PBAC noted that it would remain open to submissions from Sponsors to extend the PBS listings for any of the biologics used to treat CPP to the PASI  $\geq 12$  to  $\leq 15$  OR DLQI > 10 population at a cost-effective price in the future.

**Outcome:**

Noted

## **5 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.

## **6 Sponsor Comments**

The sponsors had no comment.