

## 5.10 RISANKIZUMAB, Injection, 75 mg in 0.83 mL pre-filled syringe, Skyrizi<sup>®</sup>, AbbVie Pty Ltd.

### 1 Purpose of Application

- 1.1 Authority Required listing for risankizumab (RIS) for treatment of severe chronic plaque psoriasis (CPP) in adults.
- 1.2 The requested basis for listing was cost-minimisation compared to ixekizumab (IXE) (Table 1).

**Table 1: Key components of the clinical issue addressed by the submission**

Component	Description
Population	Adult patients with severe chronic plaque psoriasis who have failed or are contraindicated to conventional therapy
Intervention	Risankizumab 150 mg subcutaneously at Week 0, Week 4, and then every 12 weeks thereafter
Comparator	Primary: Ustekinumab 45 mg/90 mg (weight ≤ 100 kg / > 100 kg) at week 0, week 4, and then every 12 weeks thereafter Secondary: Ixekizumab 160 mg at week 0, then 80 mg fortnightly from weeks 2 to 12, then 80 mg every 4 weeks
Outcomes	PASI 75 and PASI 90 response
Clinical claim	In patients with severe CPP, risankizumab is more effective than ustekinumab at improving PASI 90 and PASI 75 response rates, and no worse in terms of safety. Risankizumab is non-inferior to ixekizumab at improving PASI 90 and PASI 75, and no worse in terms of safety.

Source: Table 1-1, p11 of the submission.

CPP = chronic plaque psoriasis; PASI = Psoriasis Area and Severity Index

### 2 Requested listing

- 2.1 An abridged listing is provided below.

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Dispensed Price for Max. Qty	Proprietary Name and Manufacturer
RISANKIZUMAB 75 mg/0.83 mL injection, 2 x 0.83 mL syringes	1	2 <sup>a</sup> 1 <sup>b</sup>	\$ [REDACTED] (Published*)	SKYRIZI <sup>®</sup> ™, AbbVie Pty Ltd

Category/Program:	General Schedule (Code GE)
PBS indication:	Severe chronic plaque psoriasis
Treatment phase:	Initial treatment and continuing treatment
Restriction:	Authority Required - In Writing
Treatment criteria:	Must be treated by a dermatologist
Clinical criteria:	As per other PBS-listed biologics
Population criteria:	Patient must be aged 18 years or older

Source: Table 1-5, p18 of the submission.

<sup>a</sup> Initial treatment;

<sup>b</sup> Continuing treatment

\* The sponsor requested a Special Pricing Arrangement (SPA) with the effective price to be determined once confidential comparator prices are known

- 2.2 The requested listing was identical to all other biologics currently listed for CPP and the restriction criteria will be aligned with other biologics for CPP.
- 2.3 The requested quantities (including repeats) allows for up to 28 weeks of initial treatment (3 doses) followed by 24 weeks of continuing therapy (2 doses) on each prescription. The requested continuing treatment durations of 24 weeks is consistent with all listed biologics for severe CPP. The initial treatment period of 28 weeks was the same as ustekinumab (UST) and tildrakizumab (TIL), but differed to guselkumab (GUS) (20 weeks), infliximab (IFX) (22 weeks), IXE, adalimumab (ADA), etanercept (ETA) and secukinumab (SEC) (all 16 weeks).
- 2.4 A grandfathering restriction was requested to allow approximately ■■■ patients from a planned RIS Patient Familiarisation Program (PFP) and ■■■ patients enrolled in the RIS open-label extension trial (to be completed January 2022) to transition to PBS-subsidised RIS.
- 2.5 The requested PBS restriction was narrower than the proposed TGA indication with stricter criteria for prior failed therapies and disease severity. The evidence presented in the submission was in line with the TGA indication and was wider than the proposed PBS population. However, the evidence is comparable to that for the other biologics listed on the PBS for CPP.
- 2.6 The ESC noted that primary endpoints in the included trials (UltIMMa-1 & 2) were measured at 16 weeks, which is significantly shorter than the proposed length of the initial treatment period of 28 weeks. The PBAC considered an initial treatment period of 28 weeks was appropriate and consistent with the initial treatment period for UST and TIL which have a similar dosing regimen (i.e., every 12 weeks).

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

### **3 Background**

#### ***Registration status***

- 3.1 The submission was made under the TGA/PBAC Parallel Process and was not registered at the time of PBAC consideration. At the time of PBAC consideration the Clinical Evaluation Report (Round 2), Delegate's Overview and Advisory Committee on Medicines (ACM) minutes were available. The TGA Delegate recommended, and the ACM supported, the approval of RIS for the treatment of moderate to severe plaque psoriasis in adults who are candidates for phototherapy or systemic therapy.

## 4 Population and disease

- 4.1 Psoriasis is a chronic immune-mediated, painful, and disabling disease of the skin, characterised by disfiguring, scaling and erythematous plaques that may cause significant reductions in quality of life (QoL). The target population proposed for RIS is the same as that for other biologics on the PBS for severe CPP. The initial treatment criteria for PBS-listed biologics for whole body psoriasis requires patients to have a PASI >15 and have failed to achieve an adequate response, are intolerant or contraindicated to at least two of the four systemic therapies (methotrexate, cyclosporin and acitretin) and/or phototherapy.
- 4.2 RIS was proposed to be used in the same setting and line of therapy as other PBS-listed biologics for severe CPP as either monotherapy or concomitantly with other conventional therapies. If recommended, RIS would be the 11<sup>th</sup> biologic recommended for listing on the PBS for patients with severe CPP who have failed to achieve adequate response to non-biologic therapies<sup>1</sup>. RIS has a similar mode of action to GUS and TIL and would be the third IL-23 inhibitor. Listing of RIS would not change the current clinical management algorithm. Given RIS was placed in the same line as all other biologics listed on PBS for CPP, it could replace any of the listed biologics.

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

## 5 Comparator

- 5.1 The submission nominated UST as the main comparator. This was based on UST being the most commonly prescribed PBS-listed biologic for psoriasis with 41.2% market share. The submission nominated IXE as a secondary comparator (and the only one used in the cost minimisation analysis), based on IXE being the most effective of the PBS-listed biologics. Although not nominated as comparators, evidence was presented comparing RIS with other PBS-listed biologics including pharmacological analogues, GUS and TIL. The financial estimates assumed RIS will substitute for UST, SEC, GUS and IXE.
- 5.2 The PBAC considered the nominated comparators were reasonable; however, noted any of the listed biologics may be considered alternative therapies.
- 5.3 If treatment with RIS is substantially more costly than any of the alternative therapies, the PBAC could only recommend listing RIS if it is satisfied that RIS provides, for some patients, a significant improvement in efficacy or reduction of toxicity over the alternative therapies (National Health Act 1953, Section 101(3B)). The alternative therapies in this case may include ETA, ADA, IFX, UST, GUS, TIL, SEC and IXE.

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<sup>1</sup> There are currently 8 biologics listed on the PBS for CPP.

*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.

### ***Consumer comments***

6.2 The PBAC noted and welcomed the input from one health care professional via the Consumer Comments facility on the PBS website. The clinician noted the good response rates and safety profiles of the IL-23 inhibitors (GUS, TIL and RIS) and considered it beneficial for patients to have alternative treatment options within the same class available on the PBS.

### ***Clinical trials***

6.3 The submission was based on:

- A meta-analysis of two head-to-head trials comparing RIS to UST (n=997): UltIMMa-1 and 2; and
- An indirect comparison of RIS with other PBS-listed biologics for severe CPP via network meta-analyses (NMA): 60 randomised comparative trials for the short-term (10-16 weeks) outcomes and 23 trials for the long-term (44-60 weeks) outcomes.

6.4 Details of the two direct head-to-head trials and the NMA presented in the submission are provided in Table 2.

**Table 2: Trials and associated reports presented in the submission**

Trial ID	Protocol title/ Publication title	Publication citation
<b>RIS versus UST</b>		
UltIMMa-1 M16-008 1311.3	M16-008 CSR. Risankizumab versus ustekinumab and placebo comparators in a randomised double-blind trial for maintenance use in moderate to severe plaque type psoriasis (trial 1). Gordon KB, Strober B, Lebwohl M et al. Efficacy and safety of risankizumab in moderate-to-severe plaque psoriasis (UltIMMa-1 and UltIMMa-2): results from two double-blind, randomised, placebo-controlled and ustekinumab-controlled phase 3 trials. Gordon KB, Strober B, Lebwohl M et al. Efficacy and safety of risankizumab: results from two double-blind, placebo- and ustekinumab-controlled, phase 3 trials in moderate-to-severe plaque psoriasis. Gordon KB, Strober B, Lebwohl M et al. Efficacy and safety of risankizumab: results from two double-blind, placebo- and ustekinumab-controlled, phase 3 trials in moderate-to-severe plaque psoriasis.	14 Dec 2017  Lancet 2018;392(10148):650-661  The American Academy of Dermatology Annual Meeting, 16-20 Feb 2018. Acta Derm Venereol 2018;98:suppl 219:abstract P062
UltIMMa-2 M15-995 1311.28 NCT02684357	M15-995 CSR. Risankizumab versus ustekinumab and placebo comparators in a randomised double-blind trial for maintenance use in moderate to severe plaque type psoriasis (trial 2). Gordon KB, Strober B, Lebwohl M et al. Efficacy and safety of risankizumab in moderate-to-severe plaque psoriasis (UltIMMa-1 and UltIMMa-2): results from two double-blind, randomised, placebo-controlled and ustekinumab-controlled phase 3 trials. Gordon KB, Strober B, Lebwohl M et al. Efficacy and safety of risankizumab: results from two double-blind, placebo- and ustekinumab-controlled, phase 3 trials in moderate-to-severe plaque psoriasis. Gordon KB, Strober B, Lebwohl M et al. Efficacy and safety of risankizumab: results from two double-blind, placebo- and ustekinumab-controlled, phase 3 trials in moderate-to-severe plaque psoriasis.	27 Dec 2017  Lancet 2018;392(10148):650-661  The American Academy of Dermatology Annual Meeting, 16-20 Feb 2018. Acta Derm Venereol 2018;98:suppl 219:abstract P062
<b>RIS versus other PBS-listed biologics: NMA</b>		
Short-term outcomes	60 trials included in the short-term outcome analyses are presented in Table C1 of the short-term NMA report, Attachment 4 to the submission.	
Long-term outcomes	23 trials included in the long-term outcome analyses are presented in Appendix 1 of the long-term NMA report, Attachment 4 to the submission.	

Source: Table 2-3, p22 of the submission.

CSR = clinical study report; NMA = network meta-analyses; PBS = Pharmaceutical Benefits Scheme; RIS = risankizumab; UST = ustekinumab

## 6.5 The key features of the RIS randomised trials are summarised in Table 3.

**Table 3: Key features of the included randomised trials comparing RIS to UST**

Trial	N	Design/ duration of follow-up	Within trial risk of bias	Patient population	Key Outcomes
UltIMMa-1	506	R, DB, MC, 56 weeks Placebo patients crossed over to RIS at Wk 16. No switching from UST to RIS.	Low	Moderate to severe CPP; sPGA ≥ 3, PASI ≥ 12, BSA ≥ 10%	PASI 90 & sPGA 0/1 at Wk 16; PASI 75 at Wk 12; maintenance of PASI response thru to Wk 52.
UltIMMa-2	491		Low		

Source: Compiled during the evaluation from trial publications.

BSA = body surface area; CPP = chronic plaque psoriasis; DB = double blind; MC = multi-centre; PASI = Psoriasis Area and Severity Index; R = randomised; RIS = risankizumab; sPGA = static physician global assessment; UST = ustekinumab; Wk = week.

- 6.6 Both UltIMMa trials were multicentre, double-blinded and randomised patients to RIS, UST or placebo. Overall the risk of bias in the trials was considered low. Both trials had two phases; beyond the initial placebo-controlled phase, patients in the placebo groups were switched to RIS at Week 16. However, patients in the active treatment arms continued their assigned treatment at randomisation in the double-blind phase.
- 6.7 Both UltIMMa trials enrolled similar patient populations, consisting of adult patients with moderate to severe plaque psoriasis (PASI score  $\geq 12$ , body surface area (BSA) involvement  $\geq 10\%$ , and static physician global assessment (sPGA) score  $\geq 3$ ). sPGA scores of 3, 4 and 5 correspond to moderate, severe and very severe symptoms, respectively, and sPGA scores of 0-2 correspond to clear to mild symptoms.
- 6.8 The UltIMMa trial populations differed to the requested PBS population (which has stricter requirements for number of prior failed therapies and severity) but overall the trial populations were similar to other trials of biologics previously considered by the PBAC and were generally representative of the likely PBS population.
- 6.9 The submission did not present the key features of the included trials in the NMA, including patient characteristics. Neither did it provide the results of the risk of bias assessment of the included trials. The ESC noted additional information regarding the NMA was provided in the PSCR.
- 6.10 The dosing regimens of RIS and UST in the UltIMMa trials were consistent with those recommended in the (draft) product information (PI) documents. The NMA included appropriate dosage regimens for all included medicines.

### ***Comparative effectiveness***

- 6.11 The PBAC had previously based recommendations for listing of biologics for the treatment of severe CPP on the proportion of patients i) achieving and ii) maintaining a PASI 75 response ( $\geq 75\%$  improvement from baseline in the PASI score). This is also consistent with the PBS eligibility criteria for continued treatment with biologics. PASI 75 response was reported in all included trials. In addition, results were reported for PASI 90 and PASI 100 response (90% or 100% improvement from baseline in PASI score respectively), sPGA (static Physician's Global Assessment) and DLQI (Dermatology Life Quality Index).
- 6.12 The submission's clinical claims were based on the outcomes of PASI 75, PASI 90 and PASI 100 responses.

#### **Direct comparison (meta-analysis): RIS versus UST**

- 6.13 Table 4 summarises direct comparative results of PASI 75, PASI 90 and PASI 100 responses at 16 weeks for RIS versus the UST, based on the results for the intention to treat (ITT) population.

**Table 4: Meta-analyses<sup>a</sup> results of primary and key secondary efficacy outcomes across the UtiMMA trials at 16 weeks: ITT population**

Trial ID	RIS n/N (%)	UST n/N (%)	Risk difference (95% CI)	Relative risk (95% CI)	Odds ratio (95% CI)
PASI 75	538/598 (90.0)	145/199 (72.9)	<b>0.17 (0.09, 0.25)</b>	<b>1.23 (1.11, 1.36)</b>	<b>3.34 (2.03, 5.48)</b>
PASI 90	449/598 (75.1)	89/199 (44.7)	<b>0.30 (0.23, 0.38)</b>	<b>1.67 (1.42, 1.96)</b>	<b>3.72 (2.66, 5.21)</b>
PASI 100	258/598 (43.1)	36/199 (18.1)	<b>0.25 (0.18, 0.31)</b>	<b>2.35 (1.69, 3.28)</b>	<b>3.53 (2.36, 5.28)</b>
sPGA 0/1	513/598 (85.8)	124/199 (62.3)	<b>0.23 (0.16, 0.31)</b>	<b>1.38 (1.23, 1.54)</b>	<b>3.66 (2.53, 5.28)</b>
DLQI 0/1	398/598 (66.2)	89/199 (44.7)	<b>0.22 [0.14, 0.29]</b>	<b>1.48 (1.25, 1.74)</b>	<b>2.42 (1.75, 3.36)</b>

Source: Tables 2-14 to 2-16, pp40-45 of the submission.

CI = confidence interval; DLQI = Dermatology Life Quality Index; n = number of participants with event; N = total participants in group; PASI = Psoriasis Area and Severity Index; RIS = risankizumab; sPGA = static physician global assessment; UST = ustekinumab; **bold** = statistically significant

<sup>a</sup> Results meta-analysed using random effect model

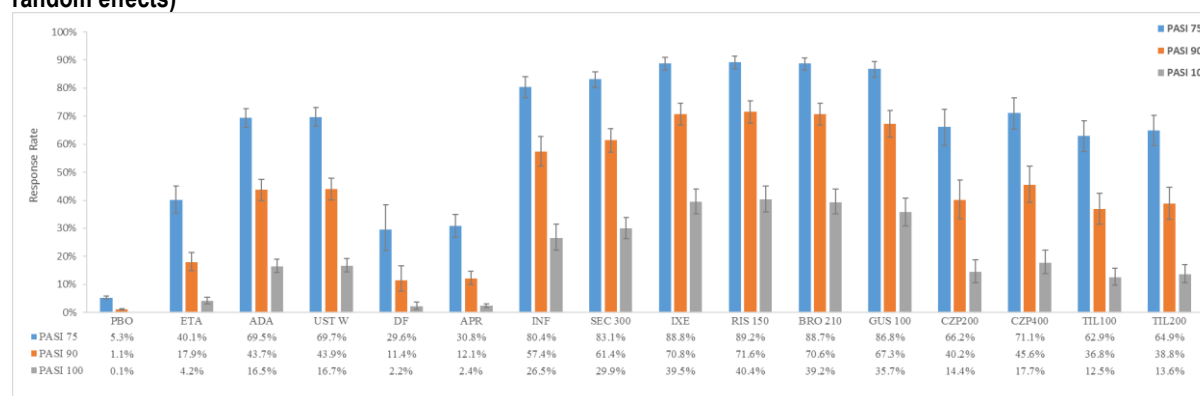
6.14 Results of the direct comparison showed a significantly greater proportion of patients receiving RIS achieved PASI 75 (relative risk (RR) 1.23, 95% CI: 1.11, 1.36), compared with patients receiving UST, after 16 weeks of therapy. Similarly, significantly higher responses were demonstrated for PASI 90 (RR 1.67, 95% CI: 1.42, 1.96) and PASI 100 (RR 2.35, 95% CI: 1.69, 3.28) in the trials at 16 weeks. Results for the sPGA and DLQI outcome measures were consistent.

6.15 The PASI responses appeared to be maintained over time with similar results shown at 52 weeks as those at 16 weeks. The PASI responses, particularly for PASI 90, seemed to continue to improve past the primary endpoint of Week 16.

Indirect comparison (NMA): RIS versus other PBS-listed biologics

6.16 Figure 1 and Table 5 summarise the NMA results of PASI 75, PASI 90 and PASI 100 responses for RIS versus all other PBS-listed biologics for severe CPP at 10-16 weeks.

**Figure 1: Estimated PASI response rates at 10-16 weeks from the NMA (base case, reference arm adjusted with random effects)**



Source: NMA of short-term PASI \_Dec 20 2018\_tildra included.xlsx, Attachment 4 to the submission

ADA = adalimumab; APR = apremilast; BRO = brodalumab; CZP = certolizumab pegol; DF = dimethyl fumarate; ETA = etanercept; GUS = guselkumab; INF = infliximab; IXE = ixekizumab; NMA = network meta-analyses; PASI = Psoriasis Area and Severity Index; PBO = placebo; RIS = risankizumab; SEC = secukinumab; TIL = tildrakizumab, PASI = Psoriasis Area and Severity Index; UST = ustekinumab

**Table 5: Pairwise comparisons of the median relative risks of achieving a PASI response at Week 10-16 with RIS versus other PBS-listed biologics for CPP**

Treatment	PASI 75		PASI 90		PASI 100	
	Median RR of (95% CrI)	Median OR of (95% CrI)	Median RR (95% CrI)	Median OR (95% CrI)	Median RR (95% CrI)	Median OR (95% CrI)
RIS	-	-	-	-	-	-
ADA						
ETA						
GUS						
INF						
IXE						
SEC						
TIL <sup>a</sup>						
UST <sup>b</sup>						

Source: Tables 2-23 and 2-24, pp54-55 of the submission, and worksheet in R CAbasecase NMA\_10-16 week analysis\_pairwise comparisons Set C in Attachment 4.

ADA = adalimumab; CPP = chronic plaque psoriasis; CrI = credible interval; ETA = etanercept; GUS = guselkumab; INF = infliximab; IXE = ixekizumab; PASI = Psoriasis Area and Severity Index; RIS = risankizumab; SEC = secukinumab; TIL = tildrakizumab; UST = ustekinumab;

<sup>a</sup> Results for tildrakizumab are for the 100 mg dose which is registered in Australia.

<sup>b</sup> Results for ustekinumab are for the reimbursed dose of 45mg for patients ≤100 kg and 90 mg for patients >100 kg

- 6.17 As shown in Figure 1, all the biologics were significantly more effective than placebo in terms of proportions of patients attaining PASI 75, 95 and 100 responses at 10-16 weeks.
- 6.18 Pairwise comparison results showed that, after 10-16 weeks of treatment, RIS was significantly more efficacious at inducing all levels of PASI response than ADA, ETA, SEC, INF, UST, and TIL. However, no significant differences were detected in any of the PASI responses when comparing RIS with IXE or GUS. The non-inferiority margin of 10% difference for the PASI 75 and PASI 90 outcomes (e.g. lower bound of the 95% CI for the RR outcome not less than 0.9) was met for the RR estimates for both outcomes. The submission nominated its non-inferiority margin (-10%) based on that reported in the GUS Public Summary Document but the ESC noted the margin should be applied to the risk difference (RD) (not the RR).
- 6.19 The relative risk estimates (RRs and odds ratios [ORs]) for RIS compared with UST were similar to those derived from direct comparative trials, although slightly higher for PASI 75. The results from the pairwise comparison were generally consistent with the results for the available comparisons in the Post Market Review of biologics for chronic plaque psoriasis in terms of the direction of the effects; however, the magnitude of the effects differed without clear pattern. Relative to the placebo arm, a smaller effect

size for IXE, SEC and INF and a bigger effect size for ADA and UST were shown in the NMA of the submission. Further, the results presented in the submission were also compatible, both in terms of direction and magnitude, with the results from another independently conducted NMA of 53 trials conducted in 2018 by the Institute for Clinical and Economic Review (1), which included the newer biologics for CPP such as GUS, TIL, and certolizumab (CERT).

- 6.20 The overall placebo group PASI 75 response differed widely across the trials included in the NMA, ranging from 0% (Papp, 2012; brodalumab trial) and 20% (Bissonnette 2013; ADA trial). In addition, there were also differences across the trials in terms of trial design, eligibility criteria and patient characteristics, all of which may impact on the placebo response rate and, consequently, the comparative effectiveness of the biologics. The pre-subcommittee response (PSCR) stated the heterogeneity was acknowledged prior to the conduct of the NMA and an adjustment was performed to account for the difference in reference arm response rates.
- 6.21 Due to limited details reported in the submission on trial selection and key trial characteristics, there were additional concerns with i) potential selection biases as no selection process of the included trials were reported; and ii) trial quality as no quality assessment of the trials was reported. The PSCR provided information regarding the conduct of the NMA including an assessment of the quality of the trials included in the analysis. The PSCR stated the risk of bias for most trials was low. While the additional information provided with the PSCR was unable to be fully evaluated, the ESC considered baseline characteristics appear comparable and the risk of bias is low for most trials.
- 6.22 During the evaluation, an indirect comparison (applying the Bucher method) of RIS versus IXE was conducted for PASI responses at 12 weeks (Week 16 results were not available for IXE), using the common reference UST. The results are presented in Table 6 below.

**Table 6: Results of the indirect comparison of RIS versus IXE for PASI responses at Week 12**

Outcome	UltiMMA-1 & 2		IXORA-S		RIS vs IXE		
	RIS n/N (%)	UST n/N (%)	IXE n/N (%)	UST n/N (%)	RD (95% CI)	OR (95% CI)	RR (95% CI)
PASI 75	525/598 (87.79)	139/199 (69.85)	120/136 (88.24)	114/166 (68.67)	-1.6% (-12.9, 9.6)	0.91 (0.44, 1.88)	0.98 (0.84, 1.14)
PASI 90	389/598 (65.05)	92/199 (46.23)	99/136 (72.79)	70/166 (42.17)	-11.8% (-25.0, 1.4)	0.59 (0.33, 1.06)	0.82 (0.63, 1.06)
PASI 100	197/598 (32.94)	37/199 (18.59)	49/136 (36.03)	24/166 (14.46)	-7.2% (-18.9, 4.5)	0.65 (0.33, 1.28)	0.71 (0.42, 1.21)

Source: Indirect comparison conducted during evaluation.

CI = confidence interval; IXE = ixekizumab; n = number of participants with event; N = total participants in group; OR = odds ratio; PASI = Psoriasis Area and Severity Index; RD = risk difference; RIS = risankizumab; RR = relative risk; UST = ustekinumab

- 6.23 Results of the indirect comparison showed that at Week 12, consistent with the results from the NMA, there were no statistically significant difference in any of the risk statistics calculated for any of the PASI responses. However, inconsistent with the results presented in the NMA, RIS appeared to be numerically worse than IXE in

achieving all levels of PASI responses in all three risk statistics calculated. Further, for both PASI 75 and PASI 90 responses, the pre-defined non-inferior margin of -10% was not met for the RD (e.g. lower bound of the 95% CI for the RD was lower than -10%) indicating RIS could potentially be inferior to IXE. Given that the PASI response for RIS appeared to keep improving beyond Week 12 in the UltIMMa trials, a comparison of PASI responses for RIS at Week 16 versus IXE at Week 12 was also conducted. Similar results, albeit a reduced between group difference for PASI 90, were produced (PASI 75: RD -2.5%, 95% CI: -13.6, 8.6; PASI 90: RD -0.3%, 95%CI: -13.4, 12.9).

- 6.24 An NMA of longer-term (week 44-60) PASI outcomes incorporating 23 trials was provided in the submission. However, caution should apply in interpreting these results since it appeared that only data from a single arm of the relevant trials were included, the outcomes were mainly measured in a non-randomised or open-label fashion and were collected at different time points in different studies, all of which may bias the NMA results. The ESC noted the longer-term NMA supported superiority of RIS compared to ADA, ETA, INF and UST and non-inferiority to GUS, IXE and SEC for the PASI 75 outcome (no data for TIL was included in the NMA).
- 6.25 The ESC considered the NMA provided supportive evidence to assess the non-inferiority of RIS and IXE.

### Comparative harms

- 6.26 Based on direct comparative data up to Week 52, RIS appears to have a similar safety profile compared to UST in any adverse events (AE), serious AE, discontinuations due to AE and serious infections (Table 7). Similar to UST, the most frequently reported AEs for RIS were viral upper respiratory tract infection and upper respiratory tract infection.

**Table 7: Summary of key adverse events from the pooled results<sup>a</sup> of the two UltIMMa trials at 52 weeks: safety set**

Trial ID	RIS n with event (%)	UST n with event (%)	RD (95% CI)	RR (95% CI)
<b>N</b>	<b>598</b>	<b>199</b>		
Any AE	419 (70.1)	157 (78.9)	-0.09 (-0.18, 0.00)	0.89 (0.78, 1.00)
Serious AE	42 (7.0)	18 (9.0)	-0.02 (-0.06, 0.03)	0.77 (0.45, 1.31)
Severe AE	31 (5.2)	11 (5.5)	0.00 (-0.05, 0.05)	0.91 (0.34, 2.44)
AE leading to discontinuation	5 (0.8)	4 (2.0)	-0.01 (-0.03, 0.01)	0.42 (0.11, 1.54)
Any AE assessed as related to study drugs	119 (19.9)	52 (26.1)	-0.06, (-0.13, 0.01)	0.76 (0.57, 1.01)
Death	2 (0.3)	0	0.00 (-0.01, 0.01)	1.69 (0.08, 35.01)
Any AE leading to death	1 (0.2)	0	0.00 (-0.01, 0.01)	1.02 (0.04, 24.76)
Any serious infection	8 (1.3)	4 (2.0)	0.00 (-0.03, 0.02)	0.63 (0.13, 3.11)

Source: Table 2-18, p47 of the submission.

AE = adverse event; CI = confidence interval; n = number of participants reporting data; N = total participants in group; RD = risk difference; RIS = risankizumab; RR = relative risk; UST = ustekinumab

<sup>a</sup> Calculated post hoc for the purpose of this submission

- 6.27 The short-term safety outcomes from pairwise comparisons in the NMA may support a conclusion of non-inferior safety for RIS versus other PBS-listed biologics. The ESC noted statistically significantly more AEs occurred in patients treated with INF, IXE and

SEC, and more patients treated with ADA, INF, IXE and SEC discontinued treatment due to an AE compared to RIS.

### Benefits/harms

6.28 A summary of the comparative benefits for RIS versus UST (direct comparison) and IXE (indirect comparison) is presented in Table 8. A summary of comparative harms of RIS versus comparators is not presented given the results support non-inferior safety. In addition, the indirect comparison via NMA presented in the submission did not allow for a quantitative comparison of the benefits and harms of RIS and other PBS-listed biologics. Accordingly, a benefits/harms table based on the NMA has not been presented.

Table 8: Summary of comparative benefits and harms for RIS versus UST and IXE

Trial	Drug	Comparator	RR (95% CI)	Event rate/100 patients			RD (95% CI)	
<b>Benefits: RIS versus UST/IXE</b>								
	RIS n/N	UST n/N	IXE n/N	RR (95% CI)	RIS n/N	UST n/N	IXE n/N	RD (95% CI)
<b>PASI 75 at Week 16: direct comparison</b>								
Pooled	538/598	145/199	-	<b>1.23</b> (1.11, 1.36)	90.0	72.9	-	<b>0.17</b> (0.11, 0.24)
<b>PASI 75 at Week 12: indirect comparison</b>								
RIS (pooled)	525/598	139/199	-	<b>1.26</b> (1.14, 1.38)	87.8	69.9	-	<b>0.18</b> (0.11, 0.25)
IXE	-	114/166	120/136	<b>1.29</b> (1.14, 1.45)	-	68.7	88.2	<b>0.20</b> (0.11, 0.28)
<b>Indirect comparison: RIS versus IXE</b>				0.98 (0.84, 1.14)				-0.02 (-0.13, 0.96)
<b>PASI 90 at Week 16: direct comparison</b>								
Pooled	449/598	89/199	-	<b>1.67</b> (1.42, 1.96)	75.1	44.7	-	<b>0.30</b> (0.24, 0.38)
<b>PASI 90 at Week 12: indirect comparison</b>								
RIS (pooled)	389/598	92/199	-	<b>1.41</b> (1.12, 1.65)	65.1	46.2	-	<b>0.19</b> (0.11, 0.27)
IXE	-	70/166	99/136	<b>1.73</b> (1.41, 2.12)	-	42.2	72.8	<b>0.31</b> (0.20, 0.41)
<b>Indirect comparison: RIS versus IXE</b>				0.82 (0.63, 1.06)				-0.12 (-0.25, 0.01)
<b>PASI 100 at Week 16: direct comparison</b>								
Pooled	258/598	36/199	-	<b>2.35</b> (1.69, 3.28)	43.1	18.1	-	<b>0.25</b> (0.18, 0.32)
<b>PASI 100 at Week 12: indirect comparison</b>								
RIS (pooled)	197/598	37/199	-	<b>1.77</b> (1.30, 2.42)	32.9	18.6	-	<b>0.14</b> (0.08, 0.21)
IXE	-	24/166	49/136	<b>2.49</b> (1.62, 3.84)	-	14.5	36.0	<b>0.212</b> (0.12, 0.31)
<b>Indirect comparison: RIS versus IXE</b>				0.71 (0.42, 1.21)				-0.07 (-0.19, 0.05)

Source: Table 2-14 to 2-16, pp40-45 of the submission, and compiled during the evaluation

CI = confidence interval; IXE = ixekizumab; n = number of participants with event; N = total participants in group; PASI = Psoriasis Area and Severity Index; RIS = risankizumab; UST = ustekinumab; RD = risk difference; RR = risk ratio; **bold** = statistically significant

- 6.29 On the basis of direct evidence presented by the submission, for every 100 patients treated with RIS in comparison to UST and over 16 weeks follow-up:
- Approximately 17 additional patients would achieve PASI 75.
  - Approximately 30 additional patients would achieve PASI 90.
  - Approximately 25 additional patients would achieve PASI 100.
- 6.30 On the basis of the evidence presented in Table 8, a similar number of patients treated with RIS or IXE would achieve a PASI 75, PASI 90 and PASI 100 response over 16 weeks of follow-up.

### ***Clinical claim***

- 6.31 The submission described RIS as:
- superior in terms of effectiveness compared with UST and non-inferior in terms of safety compared with UST;
  - non-inferior in terms of effectiveness and safety compared with IXE and GUS;
  - superior in terms of effectiveness and non-inferior in terms of safety compared with SEC, INF, ADA, ETA and TIL.
- 6.32 The PBAC considered the claim that RIS had superior effectiveness and non-inferior safety compared to UST is reasonable based on the direct evidence presented in the submission.
- 6.33 The PBAC considered the claim of non-inferior effectiveness and safety against IXE and GUS was supported by the indirect comparisons, including the NMA provided in the submission and the Bucher analyses conducted during the evaluation.
- 6.34 Although uncertain due to being based on the NMA indirect comparison, the PBAC considered the claim of superior effectiveness compared with ADA, ETA, INF, SEC and TIL may be supported. The PBAC further considered the clinical significance of any differences in effectiveness beyond 10 to 16 weeks to be uncertain. The claim of non-inferior safety compared with ADA, ETA, INF, SEC and TIL was reasonable.
- 6.35 The PBAC considered that based on extensive experience with biologics in clinical practice, its prior consideration of the relevant PBS-listed drugs for severe CPP and the data presented for RIS, there was unlikely to be any clinically significant difference in long-term outcomes between any of the PBS-listed biologic medicines available for use in CPP.

### ***Economic analysis***

- 6.36 A cost-minimisation analysis comparing RIS with IXE was presented in the submission. The analyses compared total drug costs over a 2-year treatment period (without discounting), which was consistent with the approach previously accepted by the PBAC in severe CPP.

- 6.37 The submission proposed the following equi-effective doses: RIS 150 mg at Weeks 0 and 4, then every 12 weeks = IXE 160 mg at Week 0, then 80 mg fortnightly from Weeks 2 to 12, then 80 mg every 4 weeks. The PBAC considered the equi-effective doses were reasonable.
- 6.38 IXE is currently listed on the PBS under a Special Pricing Arrangement (SPA). As the Sponsor for RIS did not have access to SPA details for IXE in CPP, the cost-minimisation analysis was based on the published price of IXE.
- 6.39 The approved ex-manufacturer price (AEMP) of RIS cost-minimised to IXE over a 104-week period was estimated to be \$4,890 per pack of two 75 mg syringes for injection, based on published prices. The DPMQ for a pack of two 75 mg injections would be \$5,041.04 based on an AEMP of \$4,890; however, the requested published DPMQ was \$ [REDACTED].
- 6.40 The submission assumed that there would be no additional administration costs for RIS compared to IXE. This was reasonable given that RIS requires fewer injections due to less frequent dosing (every 12 weeks) compared with IXE (every 4 weeks).
- 6.41 The PBAC noted IXE, GUS, TIL and CERT were recommended for listing on the basis of cost-minimisation to the least costly biologic and considered it would also be appropriate to recommend RIS on the same basis.

**Drug cost/patient: \$ [REDACTED]/year**

- 6.42 Using the requested DPMQ of \$ [REDACTED] per pack of two 75 mg injections, and assuming 10 RIS injections (20 units) per patient over the first two years (including both induction and the maintenance treatment phases), the average drug cost of RIS was estimated to be \$ [REDACTED] per patient per year. Using the published DPMQ for IXE of \$3,411.04 and assuming 29 IXE injections (30 units) per patient per year dispensed in the first two years, the average drug cost of IXE over the first two years was estimated to be \$25,582.80 per patient per year (Table 9). This cost reflects the cost per responding patient; it is noted PBS treatment is only permitted to continue if a patient achieves and maintains a PASI 75 response. The drug costs per patient differ for RIS and IXE as the requested published DPMQ for RIS does not reflect the DPMQ calculated in the economic evaluation (see paragraph 6.39).

**Table 9: Drug cost per patient for RIS and IXE over the first two years**

	RIS	IXE
Induction dose (unit)	3 (6)	7 (8)
Maintenance dose (unit)	7 (14)	22 (22)
Published DPMQ	[REDACTED]	\$3,411.04
Cost/patient over first 2 year	[REDACTED]	\$51,165.60
Average cost/patient/year	[REDACTED]	\$25,582.80

Source: calculated during the evaluation from Section 3 worksheet of the submission  
IXE = ixekizumab; RIS = risankizumab

6.43 The PBAC noted the costs presented in Table 9 were based on the published prices of RIS and IXE and that the average cost per patient per year will be lower when based on effective prices.

**Estimated PBS usage & financial implications**

6.44 This submission was not considered by DUSC. A market share approach was used to estimate the financial implications of the proposed listing. PBS claims data were used to estimate the number of scripts for all listed biologics for severe CPP and to project utilisation in the next six years as summarised in Table 10. The total biologics market for severe CPP (e.g. the total number of patients) was then calculated based on annual script number per patient for each biologic. The key assumptions in the submission’s estimates were:

- RIS would only substitute for UST (█% in Year 1 and █% from Year 2 onwards), SEC (█% in Year 1 and █% from Year 2 onwards), IXE (█% in Year 1 and █% from Year 2 onwards) and GUS (█% in Year 1 and █% from Year 2 onwards); and
- The requested listing would not grow the current market of biologics for CPP.

6.45 The estimated use and financial implications of the proposed listing of RIS is presented in Table 10.

**Table 10: Estimated use and financial implications**

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
<b>Estimated extent of use</b>						
Number of patients treated	█	█	█	█	█	█
Number of scripts dispensed <sup>a</sup>	█	█	█	█	█	█
<b>Estimated financial implications of RIS</b>						
Cost to PBS/RPBS <sup>b</sup>	█	█	█	█	█	█
Copayments	█	█	█	█	█	█
Cost to PBS/RPBS less copayments <sup>b</sup>	█	█	█	█	█	█
<b>Estimated financial implications for UST, SEC, IXE<sup>c</sup> and GUS</b>						
Cost to PBS/RPBS <sup>b</sup>	█	█	█	█	█	█
Copayments	█	█	█	█	█	█
Cost to PBS/RPBS less copayments <sup>b</sup>	█	█	█	█	█	█
<b>Net financial implications</b>						
Net cost to PBS/RPBS	█	█	█	█	█	█

Source: Tables 4-8 to 4-10, pp74-76 of the submission; Section 4 spreadsheet; and calculated during the evaluation.

GUS = guselkumab; IXE = ixekizumab; PBS = Pharmaceutical Benefits Scheme; RIS = risankizumab; RPBS = Repatriation Schedule of Pharmaceutical Benefits; SEC = secukinumab; UST = ustekinumab

<sup>a</sup> Assuming 5 scripts per year as estimated by the submission.

<sup>b</sup> RPBS costs in Table 4-10 in the submission were incorrect. Corrected in sheet ‘Section 4 Tables’ cell C146 to be =‘3b. Impact - PUB\!K26/1000. Calculation correct elsewhere in the Section 4 spreadsheet.

<sup>c</sup> The number of ixekizumab prescriptions per year (Sheet ‘2b. Scripts – market’ cell D174) was corrected from 14.5 to 7.5.

The redacted table shows that the total estimated number of patients over 6 years was less than 10,000 and the net cost to the PBS was less than \$10 million per year.

- 6.46 The PBAC noted the financial estimates presented in Table 10 are based on the published prices of RIS, UST, IXE, SEC and GUS.

### **Quality Use of Medicines**

- 6.47 The submission stated that it would be extending its existing ADA patient support program to RIS to provide support to prescribers and patients.

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

## **7 PBAC Outcome**

- 7.1 The PBAC recommended the Authority Required listing of RIS for severe CPP on a cost-minimisation basis with the least costly biologic currently listed on the PBS for CPP. In making this recommendation, the PBAC accepted any of the current PBS listed biologics for CPP could be an alternative therapy to RIS.
- 7.2 The PBAC considered the equi-effective doses of RIS and alternative biologics could be derived with reference to the Product Information and the previously recommended equi-effective doses collated in the PBS Therapeutic Relativity Sheets.
- 7.3 The PBAC noted that eight alternative biologics were listed on the PBS for the treatment of CPP at the time of consideration. The PBAC considered that while the clinical need for an additional treatment was low, the addition of another option, particularly another IL-23 inhibitor, may be useful for some patients.
- 7.4 The PBAC considered the nominated comparators of UST and IXE were reasonable; however, noted any of the listed biologic medicines may be considered alternative therapies.
- 7.5 The PBAC considered the claim that RIS is superior to UST in terms of effectiveness and non-inferior in terms of safety to be supported by the direct evidence presented. The PBAC considered the claim that RIS is non-inferior to IXE and GUS in terms of effectiveness and safety to be adequately supported by the indirect comparisons presented. However, the PBAC 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.
- 7.6 The PBAC further noted that IXE and GUS were listed for CPP on the basis of cost-minimisation to the least costly biologic and, given the non-inferiority claim supported by the submission, considered it was appropriate to list RIS on the same basis.
- 7.7 The PBAC considered that listing RIS for CPP based on a cost minimisation basis with the least costly biologic using effective prices would be cost-neutral to the PBS.
- 7.8 The PBAC considered it would be appropriate to align the listing of RIS with the other biologics for CPP, including the requested grandfather restriction and that flow-on changes to notes in the other listings to include RIS in the list of therapies would be required to facilitate the listing. The PBAC advised that grandfathered patients will be

required to meet the PBS eligibility criteria and that the grandfather restriction be removed from the listing after 12 months in line with standard procedure. The PBAC noted a number of clinical trial patients are expected to transition to PBS-subsidised RIS in January 2022. The PBAC were supportive of allowing the clinical trial patients to transition to PBS-subsidised treatment but advised that an additional submission would be required closer to the date of trial completion to extend the grandfathering clause.

- 7.9 The PBAC noted the sponsor requested consideration of a SPA and considered that, under criterion 2 of the SPA criteria, RIS has been recommended for listing in comparison with medicines that have similar arrangements.
- 7.10 Under section 101(3BA) of the *National Health Act 1953*, the PBAC advised that risankizumab may be treated as interchangeable on an individual patient basis with adalimumab, etanercept, guselkumab, infliximab, ixekizumab, secukinumab, tildrakizumab and ustekinumab for severe chronic plaque psoriasis.
- 7.11 The PBAC advised that risankizumab is not suitable for prescribing by nurse practitioners.
- 7.12 The PBAC recommended that the Early Supply Rule should apply for continuing therapy only.
- 7.13 The PBAC noted that this submission is not eligible for an Independent Review, as the PBAC has made a positive recommendation.
- 7.14 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because risankizumab is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over other biologics, or not expected to address a high and urgent unmet clinical need given the presence of alternative therapies, the criteria prescribed by the National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2009 for Pricing Pathway A were not met.

**Outcome:**

Recommended

## 8 Recommended listing

### 8.1 Add new item:

Name, Restriction, Manner of administration and form	Max. Qty	No.of Rpts	Proprietary Name and Manufacturer
RISANKIZUMAB 75 mg/0.83 mL injection, 2 x 0.83 mL syringes	1	2	SKYRIZI®/™ AbbVie Pty Ltd

<b>Condition:</b>	Severe chronic plaque psoriasis
<b>PBS Indication:</b>	Severe chronic plaque psoriasis
<b>Treatment phase:</b>	Initial treatment – Initial 1, Whole body (new patient)
<b>Restriction:</b>	<input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
<b>Treatment criteria:</b>	Must be treated by a dermatologist
<b>Clinical criteria:</b>	<p>Patient must have severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis, AND            Patient must not have received PBS-subsidised treatment with a biological medicine for this condition AND            Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 4 treatments:            (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or            (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or            (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, AND            The treatment must be as systemic monotherapy (other than methotrexate), AND            Patient must not receive more than 28 weeks of treatment under this restriction.</p>
<b>Population criteria:</b>	Patient must be aged 18 years or older.
<b>Prescriber Instructions</b>	<p>Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.</p> <p>Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.</p> <p>The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:            (a) A current Psoriasis Area and Severity Index (PASI) score of greater than 15, as assessed, preferably whilst still on treatment, but no longer than 1 month following</p>

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	<p>cessation of the most recent prior treatment.</p> <p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 1 month old at the time of application.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and</p> <p>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy]</p> <p>It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition.</p> <p>At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter.</p>
<p><b>Administrative Advice</b></p>	<p>Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (<a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a>)</p> <p>Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</p> <p>Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a></p> <p>Applications for authority to prescribe should be forwarded to:          Department of Human Services          Complex Drugs</p>

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	<p>Reply Paid 9826 HOBART TAS 7001</p> <p>No increase in the maximum quantity or number of units may be authorised. No increase in the maximum number of repeats may be authorised. Special Pricing Arrangements apply.</p>
<b>Condition:</b>	Severe chronic plaque psoriasis
<b>PBS Indication:</b>	Severe chronic plaque psoriasis
<b>Treatment phase:</b>	Treatment Phase: Initial treatment – Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years)
<b>Restriction:</b>	<input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
<b>Clinical criteria:</b>	<p>Patient must have received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle, AND            Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological medicine for this condition within this treatment Cycle, AND            Patient must not have already failed, or ceased to respond to, PBS-subsidised therapy with this drug for this condition in the current treatment cycle, AND            The treatment must be as systemic monotherapy (other than methotrexate), AND            Patient must not receive more than 28 weeks of treatment under this restriction.</p>
<b>Population criteria:</b>	Patient must be aged 18 years or older.
<b>Treatment criteria:</b>	Must be treated by a dermatologist
<b>Prescriber Instructions</b>	<p>An adequate response to treatment is defined as:</p> <p>A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline values for this treatment cycle.</p> <p>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.</p> <p>Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3 or continuing treatment restriction, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for</p>

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	<p>permanent withdrawal of treatment</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form; and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and</p> <p>(ii) details of prior biological treatment, including dosage, date and duration of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in this treatment cycle.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p> <p>At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter.</p>
<p><b>Administrative Advice</b></p>	<p>Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</p> <p>Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a></p> <p>Applications for authority to prescribe should be forwarded to:</p> <p>Department of Human Services          Complex Drugs          Reply Paid 9826          HOBART TAS 7001</p> <p>No increase in the maximum quantity or number of units may be authorised.          No increase in the maximum number of repeats may be authorised.          Special Pricing Arrangements apply.</p>

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<b>Category / Program</b>	GENERAL – General Schedule (Code GE)
<b>Prescriber Type(s)</b>	Medical Practitioners
<b>PBS Indication</b>	Severe chronic plaque psoriasis
<b>Treatment phase</b>	Initial treatment – Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years)
<b>Restriction Level / Method</b>	Authority required – in Writing
<b>Treatment criteria</b>	Must be treated by a dermatologist
<b>Clinical criteria</b>	<p>Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition</p> <p>AND</p> <p>Patient must have a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition</p> <p>AND</p> <p>The condition must have a current Psoriasis Area and Severity Index (PASI) score of greater than 15</p> <p>AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate)</p> <p>AND</p> <p>Patient must not receive more than 28 weeks of treatment under this restriction</p>
<b>Population criteria</b>	Patient must be aged 18 years or older
<b>Prescriber Instructions</b>	<p>The most recent PASI assessment must be no more than 1 month old at the time of application.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition.</p> <p>It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p>
<b>Administrative Advice</b>	<p>Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a></p> <p>Applications for authority to prescribe should be forwarded to:</p>

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	<p>Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001</p> <p>No increase in the maximum quantity or number of units may be authorised. No increase in the maximum number of repeats may be authorised. Special Pricing Arrangements apply.</p>
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<b>Condition:</b>	Severe chronic plaque psoriasis
<b>PBS Indication:</b>	Severe chronic plaque psoriasis
<b>Treatment phase:</b>	Treatment Phase: Initial treatment – Initial 1, Face, hand, foot (new patient)
<b>Restriction:</b>	<input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
<b>Clinical criteria:</b>	<p>Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis, AND Patient must not have received PBS-subsidised treatment with a biological medicine for this condition AND Patient must have failed to achieve an adequate response, as demonstrated by a Psoriasis Area and Severity Index (PASI) assessment, to at least 2 of the following 4 treatments: (i) phototherapy (UVB or PUVA) for 3 treatments per week for at least 6 weeks; and/or (ii) methotrexate at a dose of at least 10 mg weekly for at least 6 weeks; and/or (iii) cyclosporin at a dose of at least 2 mg per kg per day for at least 6 weeks; and/or (iv) acitretin at a dose of at least 0.4 mg per kg per day for at least 6 weeks, AND The treatment must be as systemic monotherapy (other than methotrexate), AND Patient must not receive more than 28 weeks of treatment under this restriction.</p>
<b>Population criteria:</b>	Patient must be aged 18 years or older.
<b>Treatment criteria:</b>	Must be treated by a dermatologist.
<b>Prescriber Instructions</b>	<p>Where treatment with methotrexate, cyclosporin or acitretin is contraindicated according to the relevant TGA-approved Product Information, or where phototherapy is contraindicated, details must be provided at the time of application.</p> <p>Where intolerance to treatment with phototherapy, methotrexate, cyclosporin or acitretin developed during the relevant period of use, which was of a severity to necessitate permanent treatment withdrawal, details of the degree of this toxicity must be provided at the time of application.</p> <p>Regardless of if a patient has a contraindication to treatment with either methotrexate, cyclosporin, acitretin or phototherapy, the patient is still required to trial 2 of these prior therapies until a failure to achieve an adequate response is met.</p> <p>The following criterion indicates failure to achieve an adequate response to prior treatment and must be demonstrated in the patient at the time of the application:</p> <p>(a) Chronic plaque psoriasis classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:            (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe, as assessed,</p>

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	<p>preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment; or</p> <p>(ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment;</p> <p>(b) A PASI assessment must be completed for each prior treatment course, preferably whilst still on treatment, but no longer than 1 month following cessation of each course of treatment.</p> <p>(c) The most recent PASI assessment must be no more than 1 month old at the time of application.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current and previous Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and</p> <p>(ii) details of previous phototherapy and systemic drug therapy [dosage (where applicable), date of commencement and duration of therapy];</p> <p>It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition. Demonstration of response should be provided within this timeframe.</p> <p>The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p> <p>At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter.</p>
<p><b>Administrative Advice</b></p>	<p>Details of the toxicities, including severity, which will be accepted as a reason for exempting a patient from the requirement for 6 weeks treatment with phototherapy, methotrexate, cyclosporin or acitretin can be found on the Department of Human Services website (<a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a>)</p> <p>Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</p> <p>Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a></p> <p>Applications for authority to prescribe should be forwarded to:</p>

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	<p>Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001</p> <p>No increase in the maximum quantity or number of units may be authorised. No increase in the maximum number of repeats may be authorised. Special Pricing Arrangements apply.</p>
<b>Condition:</b>	Severe chronic plaque psoriasis
<b>PBS Indication:</b>	Severe chronic plaque psoriasis
<b>Treatment phase:</b>	Treatment Phase: Initial treatment – Initial 2, Face, hand, foot (change or recommencement of treatment after a break of less than 5 years)
<b>Restriction:</b>	<input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
<b>Clinical criteria:</b>	<p>Patient must have received prior PBS-subsidised treatment with a biological agent for this condition in this Treatment Cycle, AND            Patient must not have already failed, or ceased to respond to, PBS-subsidised treatment with 3 biological agents for this condition within this Treatment Cycle, AND            Patient must not have already failed, or ceased to respond to, PBS-subsidised therapy with this drug for this condition in the current Treatment Cycle, AND            The treatment must be as systemic monotherapy (other than methotrexate), AND            Patient must not receive more than 28 weeks of treatment under this restriction.</p>
<b>Population criteria:</b>	Patient must be aged 18 years or older.
<b>Treatment criteria:</b>	Must be treated by a dermatologist.
<b>Prescriber Instructions</b>	<p>An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:            (i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or            (ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.</p> <p>An application for a patient who has received PBS-subsidised treatment with this drug and who wishes to re-commence therapy with this drug, must be accompanied by evidence of a response to the patient's most recent course of PBS-subsidised treatment with this drug, within the timeframes specified below.</p> <p>Where the most recent course of PBS-subsidised treatment with this drug was approved under either of the Initial 1, Initial 2, Initial 3, or continuing treatment restrictions, it is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this</p>

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	<p>condition.</p> <p>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:</p> <p>(i) the completed current Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the dates of assessment of the patient's condition; and</p> <p>(ii) details of prior biological treatment, including dosage, date and duration of treatment.</p> <p>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in this treatment cycle.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p> <p>At the time of the authority application, medical practitioners should request to provide for an initial course of this drug for this condition sufficient for up to 28 weeks of therapy, at a dose of 150 mg for weeks 0 and 4, then 150 mg every 12 weeks thereafter.</p>
<b>Administrative Advice</b>	<p>Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</p> <p>Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a></p> <p>Applications for authority to prescribe should be forwarded to:</p> <p>Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001</p> <p>No increase in the maximum quantity or number of units may be authorised. No increase in the maximum number of repeats may be authorised. Special Pricing Arrangements apply.</p>

<b>Category / Program</b>	GENERAL – General Schedule (Code GE)
<b>Prescriber Type(s)</b>	Medical Practitioners
<b>PBS Indication</b>	Severe chronic plaque psoriasis
<b>Treatment phase</b>	Initial treatment – Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years)
<b>Restriction Level / Method</b>	Authority required – in Writing
<b>Treatment criteria</b>	Must be treated by a dermatologist
<b>Clinical criteria</b>	Patient must have previously received PBS-subsidised treatment with a biological medicine for this condition

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	<p>AND Patient must have a break in treatment of 5 years or more from the most recent PBS-subsidised biological medicine for this condition</p> <p>AND The condition must be classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where: (i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or (ii) the skin area affected is 30% or more of the face, palm of a hand or sole of a foot</p> <p>AND The treatment must be as systemic monotherapy (other than methotrexate)</p> <p>AND Patient must not receive more than 28 weeks of treatment under this restriction</p>
<b>Population criteria</b>	Patient must be aged 18 years or older
<b>Prescriber Instructions</b>	<p>The most recent PASI assessment must be no more than 1 month old at the time of application.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form(s); and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed current Psoriasis Area and Severity Index (PASI) calculation sheets including the dates of assessment of the patient's condition; and</p> <p>It is recommended that an assessment of a patient's response is conducted following a minimum of 12 weeks of therapy and no later than 4 weeks from the completion of the most recent course of treatment.</p> <p>To demonstrate a response to treatment the application must be accompanied with the assessment of response from the most recent course of biological medicine therapy following a minimum of 12 weeks in therapy. It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.</p> <p>The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition within this treatment cycle.</p>
<b>Administrative Advice</b>	<p>Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a></p> <p>Applications for authority to prescribe should be forwarded to: Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001</p> <p>No increase in the maximum quantity or number of units may be authorised.</p>

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	No increase in the maximum number of repeats may be authorised. Special Pricing Arrangements apply
<b>Condition:</b>	Severe chronic plaque psoriasis
<b>PBS Indication:</b>	Severe chronic plaque psoriasis
<b>Treatment phase:</b>	Treatment Phase: Initial treatment - Initial 1, Whole body or Face, hand, foot (new patient) or Initial 2, Whole body or Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3, Whole body or Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) - balance of supply
<b>Restriction:</b>	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
<b>Population criteria:</b>	Patient must be aged 18 years or older.
<b>Treatment criteria:</b>	Must be treated by a dermatologist.
<b>Clinical criteria:</b>	<p>Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Whole body (new patient) restriction to complete 28 weeks treatment; or</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Whole body (change or recommencement of treatment after a break in biological medicine of less than 5 years ) restriction to complete 28 weeks treatment; or</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Whole body (re-commencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment; or</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 1, Face, hand, foot (new patient) restriction to complete 28 weeks treatment; or</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 2, Face, hand, foot (change or recommencement of treatment after a break in biological medicine of less than 5 years) restriction to complete 28 weeks treatment; or</p> <p>Patient must have received insufficient therapy with this drug for this condition under the Initial 3, Face, hand, foot (re-commencement of treatment after a break in biological medicine of more than 5 years) restriction to complete 28 weeks treatment; or</p> <p>AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate)</p> <p>AND</p> <p>The treatment must provide no more than the balance of up to 28 weeks treatment available under the above restrictions</p>
<b>Administrative Advice</b>	<p>Authority approval for sufficient therapy to complete a maximum of 20 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</p> <p>No increase in the maximum quantity or number of units may be authorised.</p> <p>No increase in the maximum number of repeats may be authorised.</p> <p>Special Pricing Arrangements apply.</p>

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Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer
RISANKIZUMAB 75 mg/0.83 mL injection, 2 x 0.83 mL syringes	1	1	SKYRIZI®/™ AbbVie Pty Ltd
<b>Condition:</b>	Severe chronic plaque psoriasis		
<b>PBS Indication:</b>	Severe chronic plaque psoriasis		
<b>Treatment phase:</b>	Treatment Phase: Continuing treatment, Whole body		
<b>Restriction:</b>	<input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined		
<b>Clinical criteria:</b>	Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological medicine for this condition AND Patient must have demonstrated an adequate response to treatment with this drug, AND The treatment must be as systemic monotherapy (other than methotrexate), AND Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.		
<b>Population criteria:</b>	Patient must be aged 18 years or older.		
<b>Treatment criteria:</b>	Must be treated by a dermatologist		
<b>Prescriber Instructions</b>	<p>An adequate response to treatment is defined as:            A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline values for this treatment cycle.</p> <p>The authority application must be made in writing and must include:            (a) a completed authority prescription form(s); and            (b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet including the date of the assessment of the patient's condition.</p> <p>The most recent PASI assessment must be no more than 1 month old at the time of application.</p> <p>Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.</p> <p>It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in this treatment cycle.</p>		

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	A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.
<b>Administrative Advice</b>	<p>Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</p> <p>Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a></p> <p>Applications for authority to prescribe should be forwarded to:                  Department of Human Services                  Complex Drugs                  Reply Paid 9826                  HOBART TAS 7001</p> <p>No increase in the maximum quantity or number of units may be authorised.                  No increase in the maximum number of repeats may be authorised.                  Special Pricing Arrangements apply.</p>

<b>Condition:</b>	Severe chronic plaque psoriasis
<b>PBS Indication:</b>	Severe chronic plaque psoriasis
<b>Treatment phase:</b>	Treatment Phase: Continuing treatment, Face, hand, foot
<b>Restriction:</b>	<input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
<b>Clinical criteria:</b>	<p>Patient must have received this drug as their most recent course of PBS-subsidised treatment with a biological medicine for this condition</p> <p>AND</p> <p>Patient must have demonstrated an adequate response to treatment with this drug,</p> <p>AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate),</p> <p>AND</p> <p>Patient must not receive more than 24 weeks of treatment per continuing treatment course authorised under this restriction.</p> <p>AND</p> <p>Must be treated by a dermatologist</p>
<b>Population criteria:</b>	Patient must be aged 18 years or older.
<b>Treatment criteria:</b>	Must be treated by a dermatologist
<b>Prescriber Instructions</b>	<p>An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:</p> <p>(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the pre-biological treatment baseline values; or</p> <p>(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the pre-biological treatment baseline value.</p> <p>The authority application must be made in writing and must include:</p>

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	<p>(a) a completed authority prescription form; and</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheet and face, hand, foot area diagrams including the date of the assessment of the patient's condition.</p> <p>The most recent PASI assessment must be no more than 1 month old at the time of application.</p> <p>Approval will be based on the PASI assessment of response to the most recent course of treatment with this drug.</p> <p>The PASI assessment for continuing treatment must be performed on the same affected area assessed at baseline.</p> <p>It is recommended that an application for the continuing treatment is submitted to the Department of Human Services no later than 1 month from the date of completion of the most recent course of treatment. This is to ensure continuity of treatment for those who meet the continuing restriction for PBS-subsidised treatment with this drug for this condition.</p> <p>Where a response assessment is not conducted within the required timeframe, the patient will be deemed to have failed to respond to treatment with this drug, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.</p> <p>If a patient fails to demonstrate a response to treatment with this drug under this restriction they will not be eligible to receive further PBS-subsidised treatment with this drug for this condition in this treatment cycle.</p> <p>A patient may re-trial this drug after a minimum of 5 years have elapsed between the date the last prescription for a PBS-subsidised biological medicine was approved in this cycle and the date of the first application under a new cycle under the Initial 3 treatment restriction.</p>
<p><b>Administrative Advice</b></p>	<p>Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</p> <p>Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a></p> <p>Applications for authority to prescribe should be forwarded to:</p> <p>Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001</p> <p>No increase in the maximum quantity or number of units may be authorised.</p> <p>No increase in the maximum number of repeats may be authorised.</p> <p>Special Pricing Arrangements apply.</p>

<p><b>Condition:</b></p>	<p>Severe chronic plaque psoriasis</p>
<p><b>PBS Indication:</b></p>	<p>Severe chronic plaque psoriasis</p>
<p><b>Treatment phase:</b></p>	<p>Treatment Phase: Continuing treatment, Whole body or Continuing treatment, Face, hand, foot – balance of supply</p>

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<b>Restriction:</b>	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input checked="" type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
<b>Clinical criteria:</b>	<p>Patient must have received insufficient therapy with this drug under the Continuing treatment, Whole body restriction to complete 24 weeks treatment; OR            Patient must have received insufficient therapy with this drug under the Continuing treatment, Face, hand, foot restriction to complete 24 weeks treatment,            AND            The treatment must provide no more than the balance of up to 24 weeks treatment available under the above restrictions,            AND            The treatment must be as systemic monotherapy (other than methotrexate).</p>
<b>Population criteria:</b>	Patient must be aged 18 years or older.
<b>Treatment criteria:</b>	Must be treated by a dermatologist
<b>Administrative Advice</b>	<p>Note            Authority approval for sufficient therapy to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday)</p> <p>No increase in the maximum quantity or number of units may be authorised.            No increase in the maximum number of repeats may be authorised.            Special Pricing Arrangements apply.</p>

Grandfathered patients

<b>Category/ Program</b>	GENERAL - General Schedule (Code GE)
<b>Prescriber Type(s)</b>	Medical Practitioners
<b>PBS Indication</b>	Severe chronic plaque psoriasis
<b>Treatment phase</b>	Initial treatment - Whole body, Grandfathered patients
<b>Restriction Level / Method</b>	Authority required –In Writing
<b>Treatment criteria</b>	Must be treated by a dermatologist
<b>Clinical criteria</b>	<p>Patient must have-severe chronic plaque psoriasis where lesions have been present for at least 6 months from the time of initial diagnosis; AND            Patient must have received non-PBS subsidised therapy with this drug for this condition prior to [insert date]; AND            Patient must have had a Psoriasis Area and Severity Index (PASI) score of greater than 15 prior to commencing treatment with this drug for this condition; AND            Patient must have demonstrated a response to treatment as specified in the criterion included in the restriction for continuing PBS-subsidised treatment with this drug for this condition (whole body); AND            Patient must have demonstrated an adequate response following at least 12 weeks of non-PBS subsidised treatment with this drug for this condition; AND            The treatment must be as systemic monotherapy (other than methotrexate); AND            Patient must not receive more than 24 weeks of treatment under this restriction</p>
<b>Population criteria</b>	Patient must be aged 18 years or older
<b>Prescriber Instructions</b>	<p>An adequate response to treatment is defined as:            A Psoriasis Area and Severity Index (PASI) score which is reduced by 75% or more, or is sustained at this level, when compared with the baseline values for this treatment cycle.</p>

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	<p>The authority application must be made in writing and must include:;</p> <p>(a) a completed authority prescription form(s); and,</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the following:;</p> <p>(i) the completed Psoriasis Area and Severity Index (PASI) calculation sheets including the date of the assessment of the patient's condition at baseline (prior to initiation of non-PBS subsidised therapy with this drug) and the most recent PASI assessment; and</p> <p>(iii) the completed PASI calculation sheet demonstrating response.</p> <p>The most recent PASI assessment must be no more than 1 month old at the time of application.</p> <p>A Grandfather patient may qualify for PBS-subsidised treatment under this restriction once only.</p> <p>For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.</p>
<b>Administrative Advice</b>	<p>Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</p> <p>Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a></p> <p>Applications for authority to prescribe should be forwarded to:                  Department of Human Services                  Complex Drugs                  Reply Paid 9826                  HOBART TAS 7001</p>

<b>Category / Program</b>	GENERAL - General Schedule (Code GE)
<b>Prescriber Type(s)</b>	Medical Practitioners
<b>PBS Indication</b>	Severe chronic plaque psoriasis
<b>Treatment phase</b>	Initial treatment – Face, hand, foot, Grandfathered patients
<b>Restriction Level / Method</b>	Authority required – in Writing
<b>Treatment criteria</b>	Must be treated by a dermatologist
<b>Clinical criteria</b>	<p>Patient must have severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where lesions have been present for at least 6 months from the time of initial diagnosis; AND</p> <p>Patient must have received non-PBS subsidised therapy with this drug for this condition prior to [insert date]; AND</p> <p>Patient must have had disease, prior to treatment with this drug for this condition, classified as severe due to a plaque or plaques on the face, palm of a hand or sole of a foot where:</p> <ul style="list-style-type: none"> <li>(i) at least 2 of the 3 Psoriasis Area and Severity Index (PASI) symptom subscores for erythema, thickness and scaling were rated as severe or very severe; or</li> <li>(ii) the skin area affected was 30% or more of the face, palm of a hand or sole of a foot</li> </ul> <p>Patient must have demonstrated an adequate response following at least 12 weeks of non-PBS subsidised treatment with this drug for this condition; AND</p> <p>The treatment must be as systemic monotherapy (other than methotrexate); AND</p> <p>Patient must not receive more than 24 weeks of treatment under this restriction</p>
<b>Population criteria</b>	Patient must be aged 18 years or older

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<p><b>Prescriber Instructions</b></p>	<p>An adequate response to treatment is defined as the plaque or plaques assessed prior to biological treatment showing:</p> <p>(i) a reduction in the Psoriasis Area and Severity Index (PASI) symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the baseline values; or</p> <p>(ii) a reduction by 75% or more in the skin area affected, or sustained at this level, as compared to the baseline value for this treatment cycle.</p> <p>The PASI assessment must be performed on the same affected area as assessed at baseline or prior to initiation of treatment with this drug.</p> <p>The authority application must be made in writing and must include:</p> <p>(a) a completed authority prescription form(s); and,</p> <p>(b) a completed Severe Chronic Plaque Psoriasis PBS Authority Application - Supporting Information Form which includes the completed Psoriasis Area and Severity Index (PASI) calculation sheets and face, hand, foot area diagrams including the date of the assessment of the patient's condition at baseline (prior to initiation of therapy with this drug) and the most recent PASI assessment.</p> <p>A Grandfathered patient may qualify for PBS-subsidised treatment under this restriction once only.</p> <p>For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.</p>
<p><b>Administrative Advice</b></p>	<p>Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</p> <p>Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at <a href="http://www.humanservices.gov.au">www.humanservices.gov.au</a></p> <p>Applications for authority to prescribe should be forwarded to:</p> <p>Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001</p>

8.2 Amend NOTE for PBS item codes: 9426D, 9428F, 9425C, 9427E, 11223Q, 9037P, 9429G, 11221N, 11222P, 9461Y, 9462B, 11224R, 11225T, 9091L, 9431J, 11614G, 11590B, 11595G, 11605T, 11606W, 5758C, 9617E, 11032P, 11033Q, 10425Q, 10494H, 10910F, 11613F, 11616J, 9304Q, 9305R.

Additions in italics.

#### TREATMENT OF ADULT PATIENTS WITH SEVERE CHRONIC PLAQUE PSORIASIS

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines adalimumab, etanercept, guselkumab, infliximab, ixekizumab, *risankizumab*, secukinumab, tildrakizumab and ustekinumab for adult patients with severe chronic plaque psoriasis. Therefore, where the term 'biological medicines' appears in notes and restrictions, it refers to adalimumab, etanercept, guselkumab, infliximab, ixekizumab, *risankizumab*, secukinumab, tildrakizumab and ustekinumab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the above biological medicines at any 1 time.

A patient who received PBS-subsidised adalimumab, etanercept, guselkumab, infliximab, ixekizumab, *risankizumab*, secukinumab, tildrakizumab and ustekinumab treatment prior to *1 February 2019 [risankizumab listing date]* is considered to start their first cycle as of *1 February 2019 [risankizumab listing date]*.

A patients receiving PBS-subsidised treatment for chronic plaque psoriasis is able to commence a 'treatment cycle', where they may trial biological medicines without having to experience a disease flare, when swapping to an alternate biological medicine. Under these arrangements, within a single cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.

Serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment, including serious infusion or injection related reactions, Steven's Johnson Syndrome, development of a demyelinating lesion, progressive multifocal leukoencephalopathy and malignancy related to treatment with the biological medicine, is not considered as a treatment failure.

A patient must be assessed for response to each course of treatment according to the criteria included in the relevant continuing treatment restriction.

Once a patient has either failed or ceased to sustain a response to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised biological medicine therapy before they are eligible to commence the next cycle.

The duration of the break in therapy will be measured from the date the last prescription for

PBS-subsidised treatment was approved in the most recent cycle to the date of the first application for initial treatment with a biological medicine under the new cycle.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of more than 5 years may commence a new treatment cycle under Initial 3 treatment restriction.

A patient who has failed fewer than 3 biological medicines in a treatment cycle and who has a break in therapy of less than 5 years may commence a further course of treatment within the same treatment cycle under Initial 2 treatment restriction.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

How to prescribe PBS-subsidised biological medicine treatment for severe chronic plaque psoriasis.

There are separate restrictions for both the initial and continuing treatment for psoriasis affecting the whole body, versus psoriasis affecting the face, hands and feet.

(1) Initial treatment.

An application for initial treatment should be made where:

(i) a patient has not received prior PBS-subsidised biological medicine treatment for this condition and wishes to commence such therapy (Initial 1 - New patient); or

(ii) a patient wishes to recommence treatment with a biological medicine following a break in PBS-subsidised therapy of more than 5 years (Initial 3 - Recommencement of treatment after a break in biological medicine of more than 5 years); or

(iii) a patient who has received prior PBS-subsidised biological medicine therapy for this condition (initial or continuing) and wishes to trial an alternate biological medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years) [further details are under (4) 'Swapping therapy' below]; or

(iv) a patient wishes to recommence treatment with a specific biological medicine following a break in PBS-subsidised therapy of less than 5 years with the same medicine (Initial 2 - Change or Re-commencement of treatment after a break in biological medicine of less than 5 years).

An application for initial treatment will be limited to provide for a maximum of 16 weeks of therapy for adalimumab, etanercept, ixekizumab and secukinumab, 20 weeks of therapy for guselkumab, 22 weeks of therapy for infliximab and 28 weeks of therapy for *risankizumab*, *tildrakizumab* and *ustekinumab*.

It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.

Grandfather patients (guselkumab only).

A patient who commenced treatment with guselkumab for chronic plaque psoriasis prior to (1 February 2019) and who continues to receive treatment at the time of application, may

qualify for treatment under the Initial treatment - Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

*Grandfather patients (tildrakizumab only).*

A patient who commenced treatment with tildrakizumab for chronic plaque psoriasis prior to (1 February 2019) and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.

For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.

*Grandfather patients (risankizumab only).*

*A patient who commenced treatment with risankizumab for chronic plaque psoriasis prior to [risankizumab listing date] and who continues to receive treatment at the time of application, may qualify for treatment under the Initial treatment Grandfather treatment restriction.*

*A patient may only qualify for PBS-subsidised treatment under this restriction once. A maximum of 24 weeks of treatment will be authorised under this criterion. Following completion of the initial PBS-subsidised course, further subsidised treatment must be prescribed under the continuing treatment restriction of the relevant drug. 'Grandfather' arrangements will only apply for the first treatment cycle.*

*For the second and subsequent cycles, a 'grandfather' patient must qualify for continuing treatment under the criteria that apply to a continuing patient.*

(2) Assessment of response to initial treatment.

When prescribing initial treatment with a biological medicine, it is recommended that a PASI assessment is conducted after at least 12 weeks of treatment. This assessment must be conducted within 1 month of the completion of this initial treatment course.

The PASI assessment for continuing treatment must be performed on the same affected area as assessed at baseline.

(3) Continuing treatment.

Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.

A patient must be assessed for response to a course of continuing therapy, and the assessment must be submitted to the Department of Human Services where applicable. Where a response assessment is not submitted where applicable, the patient will be deemed to have failed to respond to treatment with that biological medicine, unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

Infliximab and etanercept only:

For the first continuing treatment course of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed for response following a minimum of 12 weeks of therapy under the Initial 1 or Initial 2 treatment restrictions.

For second and subsequent continuing courses of PBS-subsidised biological medicine treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment.

(4) Swapping therapy.

Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine without having to requalify with respect to the indices of disease severity (i.e. a PASI score of greater than 15), or the prior non-biological therapy requirements, except if the patient has had a break in therapy of more than 5 years who would need to requalify with respect to the indices of disease severity.

A patient who is not able to complete a minimum of 12 weeks of an initial treatment course will be deemed to have failed treatment with that biological medicine unless the patient has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment.

A patient may trial an alternate biological medicine at any time, regardless of whether they are receiving therapy (initial or continuing) with a biological medicine at the time of the application. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that particular biological medicine within the same cycle.

To ensure a patient receives the maximum treatment opportunities allowed under these arrangements, it is important that they are assessed for response to every course of treatment.

(5) Baseline measurements to determine response.

The Department of Human Services will determine whether a response to treatment has been

demonstrated based on the baseline PASI assessment submitted with the first authority application for a biological medicine. However, prescribers may provide new baseline PASI assessments any time that an initial or change or recommencement treatment application is submitted within a treatment cycle and this revised baseline PASI score will be used to assess the patient's response to the PBS-subsidised treatment.

To ensure consistency in determining response, the same body area assessed at the baseline PASI assessment must be assessed for demonstration of response to treatment for the purposes of all continuing treatments.

(6) Recommencement of treatment after a 5-year break in PBS-subsidised therapy.

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised biological therapy of at least 5 years, must qualify under Initial 3 treatment according to the criteria of the relevant restriction and index of disease severity. A PASI assessment must be conducted prior to application and patient must have a PASI score of greater than 15 for whole body. For the face, hand, foot at least 2 of the 3 the PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe; or the skin area affected is 30% or more of the face, palm of a hand or sole of a foot. The PASI assessment must be no older than 1 month at the time of application.

## **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.