5.18 BIMEKIZUMAB, Injection 320 mg in 2 mL single use pre-filled pen, Bimzelx®, UCB AUSTRALIA PROPRIETARY LIMITED

1 Purpose of Submission

1.1 The Category 4 submission requested to list bimekizumab injection 320 mg in 2 mL single use pre-filled pen (Bimzelx®) under the same circumstances as the PBS-listed bimekizumab injection 160 mg in 1 mL single use pre-filled pen for the treatment of severe chronic plaque psoriasis (CPP).

1.2 The listing was requested on a cost-minimisation basis approach versus bimekizumab injection 160 mg in 1 mL single use pre-filled pen.

2 Background

2.1 Bimekizumab 160 mg/1 mL injection, 2 x 1 mL pen device is currently listed on the PBS as an Authority Required listing for severe chronic plaque psoriasis.

2.2 Bimekizumab 160 mg/1 mL injection, 2 x 1 mL pen device/syringe and bimekizumab 320 mg/2 mL injection, 1 x 2 mL pen device/syringe were recommended by the PBAC in its May 2025 meeting for moderate to severe hidradenitis suppurativa.

Registration status

2.3 Bimekizumab (Bimzelx®) 160 mg/1 mL pre-filled syringe or pen and 320 mg/2 mL prefilled syringe or pen was registered in the Australian Register of Therapeutic Goods by the TGA on 8 April 2025 for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.

2.4 Bimekizumab (Bimzelx®) is indicated for the treatment of adult patients with active psoriatic arthritis who had an inadequate response to or who had been intolerant to previous disease modifying antirheumatic drug (DMARD) therapy.

2.5 Bimekizumab (Bimzelx®) is indicated for the treatment of adult patients with active non-radiographic axial spondyloarthritis with objective signs of inflammation as indicated by elevated C reactive protein (CRP) and /or magnetic resonance imaging (MRI) who had an inadequate response to or are intolerant to nonsteroidal anti-inflammatory drugs (NSAIDs).

2.6 Bimekizumab (Bimzelx®) is indicated for the treatment of adult patients with active ankylosing spondylitis who had responded inadequately or were intolerant to conventional therapy.

2.7 Bimekizumab (Bimzelx®) is indicated for the treatment of adult patients with moderate to severe hidradenitis suppurativa with an inadequate response to conventional systemic HS therapy.

2.8 The recommended doses for severe plaque psoriasis and hidradenitis suppurativa is 320 mg.

2.9 For patients with psoriatic arthritis and coexistent moderate to severe plaque psoriasis, the dosing regimen used for plaque psoriasis may be considered: 320 mg (administered either as two subcutaneous injections of 160 mg or one injection of 320 mg) at Week 0, 4, 8, 12, 16, and then every 8 weeks thereafter. After Week 16, regular assessment of joint efficacy is recommended. If a sufficient clinical response cannot be maintained, switching to 160 mg every 4 weeks may be considered.

Previous PBAC consideration

2.10 Bimekizumab 160 mg in 1 mL single use pre-filled pen and pre-filled syringe was previously considered for chronic plaque psoriasis by the PBAC at its March 2023 meeting. The PBAC recommended the Authority Required listing of bimekizumab for the treatment of severe CPP.

3 Requested listing

3.1 The submission requested the following:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
BIMEKIZUMAB					
Initial treatment					
bimekizumab 160 mg/mL injection, 2 x 1 mL pen devices	13644D	1	2	4	Bimzelx
bimekizumab 320 mg/2mL injection, 1 x 2 mL pen devices	*NEW*	*1*	*1*	*4*	
Continuing treatment					
bimekizumab 160 mg/mL injection, 2 x 1 mL pen devices	13652M	1	2	2	
bimekizumab 320 mg/2mL injection, 1 x 2 mL pen devices	*NEW*	*1*	*1*	*2*	
8050	**Indication:** Severe chronic plaque psoriasis				

3.2 The submission originally requested the two forms, 160 mg/1 mL and 320 mg/2 mL be 'a-flagged' in the schedule (i.e. being substitutable at the pharmacy level). However, following feedback during the evaluation indicating that a-flagging is not feasible across different strengths—since they will be listed with varying maximum quantities—the sponsor acknowledged and agreed with this advice in its pre-PBAC response.

3.3 The submission proposed an effective AEMP for one bimekizumab 320 mg/2 mL prefilled pen of $[redacted] and the published AEMP of $3,260.00.

4 Comparator

4.1 The submission proposed a new strength of bimekizumab and nominated the currently listed strength (160 mg/1 mL) of the same drug as the comparator.

4.2 In March 2023, PBAC first recommended bimekizumab 160 mg/1 mL pre-filled pen for the treatment of severe chronic plaque psoriasis. It was compared to all other PBS-listed biologic disease-modifying anti-rheumatic drugs (bDMARDs) for CPP: adalimumab (ADA), guselkumab (GUS), ixekizumab (IXE), risankizumab (RIS), secukinumab (SEC), ustekinumab (UST), tildrakizumab (TIL), etanercept (ETN) and infliximab (IFX).

5 Consideration of the evidence

Sponsor hearing

5.1 There was no hearing for this item.

Consumer inputs

5.2 The PBAC noted the advice received from The Australasian College of Dermatologists regarding use of bimekizumab 320 mg/2 mL in clinical practice. The PBAC specifically noted the advice that the use of bimekizumab 320 mg/2 mL injection will enable patients to have a single injection as opposed to two, improving adherence, safety and reducing needle anxiety. The PBAC noted that this advice was supportive of the evidence provided in the submission.

Clinical trials

5.3 The submission was based on Study UP0119, a Phase 1, open-label, randomised, parallel-group bioequivalence study. The study enrolled healthy volunteers aged 18 to 65 years. 71 total patients were randomised to receive either a one injection with bimekizumab 320 mg/2 mL prefilled pen or two injections with bimekizumab 160 mg/1 mL prefilled pen. The primary objective of UP0119 was to compare the pharmacokinetic parameters between the two treatments with a view to demonstrate bioequivalence.

5.4 Two other studies (UP0068, UP0074) were included in the submission documents.

5.5 UP0068 was an open-label, randomized, parallel group, single-dose bioequivalence study of bimekizumab given as 1x2mL or 2x1ml subcutaneous injections in healthy study participants.

5.6 This study did not evaluate autoinjector pens and as the submission notes (Main body of the submission), this study was terminated early due to the COVID-19 pandemic.

5.7 UP0074 was an open label, randomized, parallel-group, single-dose study to evaluate the pharmacokinetics, safety, and tolerability of bimekizumab given as 2x1mL or 1x2mL subcutaneous injections in healthy subjects.

5.8 This study did not evaluate the bioequivalence of bimekizumab 160ml/1mL vs 320mg/2mL pre-filled pens and noted that cohort one had a protocol deviation of excessive injection force, which could have affected the PK objective of the study. (Appendix 6 of the submission)

Table 1: Trials and associated reports presented in the submission

Trial ID	Protocol title/ Publication title	Publication citation
Direct randomised trials		
Study UP0119 (pivotal study) NCT05292131	UCB Biopharma SRL. A Bioequivalence Study of Bimekizumab Given as 1x2mL or 2x1mL Subcutaneous Injection Using an Autoinjector in Healthy Study Participants: 121 Healthy volunteers, Aged 18-65 years	09 Jan 2023

Source: Table 2.1, p7 of the submission.

5.9 As a Category 4 submission, no evaluation of the clinical evidence was undertaken.

Comparative effectiveness

5.10 In December 2024, the TGA Delegate's overview accepted the bioequivalence of bimekizumab 320/2mL to 160/1mL x 2, noting that:

> "Based on the submitted bioequivalence studies the delegate is satisfied that the bimekizumab pre-filled pen 160mg (1mL x 2) injected twice subcutaneously has adequately demonstrated bioequivalence to the bimekizumab pen 320mg (2mL) pre-filled syringe injected once subcutaneously." (Appendix 2 of the submission).

Comparative harms

5.11 As stated above, the TGA Delegate's overview in December 2024 was satisfied that bimekizumab 320mg/2mL is bioequivalent to 160mg/1mL x2.

Clinical claim

5.12 The submission claimed non-inferior comparative effectiveness and non-inferior comparative safety of one bimekizumab 320 mg/2 mL prefilled pen compared with two bimekizumab 160 mg/1 pre-filled pens.

5.13 The PBAC considered that the claim of non-inferior comparative effectiveness was reasonable.

5.14 The PBAC considered that the claim of non-inferior comparative safety was reasonable.

Economic analysis

5.15 As a Category 4 submission, the economic analysis was not independently evaluated.

5.16 The submission presented a cost-minimisation approach of bimekizumab 320 mg/2 mL prefilled pen compared with two bimekizumab 160 mg/1 mL prefilled pens.

5.17 The recommended dosing regimen outlined in the bimekizumab PI (Appendix 1 of the submission):

- One bimekizumab 320 mg/2 mL administered by subcutaneous injection at Week 0, 4, 8, 12, 16 and every 8 weeks thereafter.
- Two bimekizumab 160 mg/1 mL pre-filled pens administered by subcutaneous injection at Week 0, 4, 8, 12, 16 and every 8 weeks thereafter.

Drug cost/patient/year: $[redacted]

5.18 The estimated drug cost/patient/year would be $[redacted], based on a 2-year duration for the treatment of severe CPP, using the proposed effective AEMP price of one bimekizumab 320 mg/2mL prefilled pen.

Estimated PBS usage and financial implications

5.19 Refer to Table 2 which presents the estimated extent of use, cost of bimekizumab 320 mg/2 mL prefilled pen to the PBS/RPBS and the net financial implications to the PBS/RPBS and MBS. The financial impact to Services Australia will be determined by that agency as part of the post PBAC process.

5.20 The submission estimated that 100,000 to < 200,000 scripts would be supplied bimekizumab 320 mg/2 mL over the first six years of listing (500 to < 5,000 in Year 1 to 30,000 to < 40,000 in Year 6).

- The submission stated that the estimated net financial impact to the PBS/RPBS for the listing of bimekizumab 320 mg/2 mL is $0 to < $10 million over six years (Year 1 $0 to < $10 million to Year 6 $0 to < $10 million).
- The evaluation assessed the model structure as acceptable and noted that if the price per unit remains unchanged (i.e., 1 x 320 mg equals 2 x 160 mg), there will be no additional costs to Health and portfolio agencies.
- The PBAC advised that the claim of a $0 to < $10 million financial impact was reasonable.

Table 2: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use						
Number of scripts dispensed[a]	[redacted][1]	[redacted][2]	[redacted][2]	[redacted][3]	[redacted][4]	[redacted][4]
Estimated financial implications of bimekizumab 320mg/2ml prefilled pen						
Cost to PBS/RPBS less co-payment	$[redacted][5]	$[redacted][6]	$[redacted][7]	$[redacted][8]	$[redacted][9]	$[redacted][10]
Estimated financial implications of bimekizumab 160mg/1ml 2 prefilled pens						
Cost to PBS/RPBS less co-payment	-$[redacted][5]	-$[redacted][6]	-$[redacted][7]	-$[redacted][8]	-$[redacted][9]	-$[redacted][10]
Net financial implications						
Net cost to PBS/RPBS	$[redacted][5]	$[redacted][5]	$[redacted][5]	$[redacted][5]	$[redacted][5]	$[redacted][5]

[a] Assuming 7.5 scripts per patient per year as estimated by the submission.
Abbreviations: MBS = Medical Benefits Scheme; PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme.
Source: Sheet 5 of the Utilisation and Cost Model Workbook.
The redacted values correspond to the following ranges:
[1]5,000 to < 10,000
[2]10,000 to < 20,000
[3]20,000 to < 30,000
[4]30,000 to < 40,000
[5]$0 to < $10 million
[6]$10 million to < $20 million
[7]$20 million to < $30 million
[8]$30 million to < $40 million
[9]$40 million to < $50 million
[10]$50 million to < $60 million

At year 6, the estimated number of patients was 30,000 to < 40,000 and the net cost to the PBS was to be $0 to < $10 million.

6 PBAC Outcome

6.1 The PBAC recommended the listing of bimekizumab 320 mg in 2 mL single use prefilled pen for the treatment of severe CPP under the same circumstances as bimekizumab 160 mg in 1 mL single use prefilled pen.

6.2 The PBAC accepted the proposed cost-minimisation approach with the equi-effective doses being bimekizumab 320 mg and 2 x bimekizumab 160 mg.

6.3 The PBAC considered the utilisation, financial estimates, and estimated net financial impact to the PBS/RPBS over the first six years of listing, to be reasonable. The PBAC supported the submission's estimate that the listing was expected to result in $0 to < $10 million financial impact based on the assumption that bimekizumab 320 mg/2 mL pre-filled pen is expected to only substitute for bimekizumab 160 mg/1 mL pre-filled pen in severe CPP requiring a 320mg dose.

6.4 The PBAC considered bimekizumab 160 mg/1 mL was the appropriate comparator as bimekizumab 320 mg/2 mL was expected to directly replace bimekizumab 2 quantities of 160 mg/1 mL. The PBAC noted bimekizumab 320 mg/2 mL may offer a benefit of fewer injections for patients currently using bimekizumab 160 mg/1 mL.

6.5 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because bimekizumab 320 mg/2 mL is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over bimekizumab 160 mg/1 mL pre-filled pen, nor expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met.

Outcome:
Recommended

7 Recommended listing

Add new item as follows:

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Initial treatment					
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bimekizumab 320 mg/2mL injection, 1 x 2 mL pen devices	*NEW*	*1*	*1*	*4*	
Continuing treatment					
bimekizumab 160 mg/mL injection, 2 x 1 mL pen devices	13652M	1	2	2	
bimekizumab 320 mg/2mL injection, 1 x 2 mL pen devices	*NEW*	*1*	*1*	2	
8050	**Indication:** Severe chronic plaque psoriasis				

* The full restrictions weren't populated for brevity reasons as there will be no changes to the restrictions. The existing listings for CPP include face, hand, foot and whole body - CPP dosing regimen is the same across body areas.

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

9 Context for Decision

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

10 Sponsor's Comment

UCB Australia extends our appreciation to the Australasian College of Dermatologists for providing expert advice on the patient value of bimekizumab 320 mg/2 mL injection. We also acknowledge the PBAC for recognising these highly patient-relevant benefits and look forward to working collaboratively with the Department of Health, Disability and Ageing to facilitate timely and equitable access for Australian patients.