

5.22 DUPILUMAB, Injection 200 mg in 1.14 mL single dose pre-filled pen Injection 300 mg in 2 mL single dose pre-filled pen Dupixent[®], Sanofi-Aventis Australia Pty Ltd

1 Purpose of Submission

- 1.1 The Category 4 submission requested a General Schedule Authority Required listing of two new forms of dupilumab, 200 mg in 1.14 mL and 300 mg in 2 mL single dose pre-filled pen/autoinjector (hereafter referred to as dupilumab PFP) for the treatment of severe atopic dermatitis (AD) in patients aged less than 12 years.
- 1.2 The submission also requested a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing of dupilumab PFP for the treatment of uncontrolled severe asthma in patients aged 6 to 11 years.
- 1.3 Listing was requested on the basis of a cost-minimisation basis versus dupilumab 200 mg in 1.14 mL and 300 mg in 2 mL single dose pre-filled syringe (hereafter referred to as dupilumab PFS). The key components of the proposed listing are provided Table 1 below.

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

Component	Description
Population	Chronic severe atopic dermatitis in paediatric patients (less than 12 years of age); AND Uncontrolled severe asthma in paediatric patients (6 to 11 years of age)
Intervention	Dupilumab 300 mg in 2 mL pre-filled pen and 200 mg in 1.14 mL pre-filled pen
Comparator	AD: Dupilumab 300 mg in 2 mL pre-filled syringe with needle shield and 200 mg in 1.14 mL pre-filled syringe with needle shield Uncontrolled severe asthma: Dupilumab 300 mg in 2 mL and 200 mg in 1.14 mL pre-filled syringe with needle shield
Outcomes	Pharmacokinetics (co-primary), safety (co-primary), immunogenicity (secondary) comparative efficacy (exploratory)
Clinical claim	Non-inferiority

Source: Table 1.1 of the submission main body.

2 Background

- 2.1 Dupilumab PFS is currently listed on the PBS as a General Schedule Authority Required listing for chronic severe AD in patients aged 12 years and older and a Section 100 (Highly Specialised Drugs Program) Authority Required listing for uncontrolled severe asthma in patients aged 12 years and older.

Registration status

- 2.2 Dupilumab PFP was TGA registered on 3 June 2022 for the treatment of the following:
- Atopic dermatitis (in adult and paediatric patients aged 2 years and older) - the approved product information (PI) states that the pre-filled pen is not intended for use in children below 2 years of age (Pg 3, approved PI of dupilumab PFP).
 - Prurigo nodularis
 - Asthma (in patients aged 6 years and older)
 - Chronic rhinosinusitis with nasal polyposis (CRSwNP)

Previous PBAC consideration

- 2.3 Dupilumab PFP has not been previously considered by the Pharmaceutical Benefits Advisory Committee (PBAC) for the treatment of AD and uncontrolled severe asthma in the paediatric population.
- 2.4 At its November 2022 meeting, the PBAC recommended the listing of the new form of dupilumab PFP for severe AD and uncontrolled severe asthma in patients 12 years and over. This recommendation has not yet been implemented.
- 2.5 Dupilumab (PFS) was first recommended by the PBAC at its March 2020 meeting for the treatment of patients aged 12 years and older with severe atopic dermatitis (AD) who are inadequately controlled on topical therapies. It was subsequently listed on the PBS on 1 March 2021.
- 2.6 At its November 2020 meeting, the PBAC recommended dupilumab PFS for the treatment of uncontrolled severe allergic or eosinophilic asthma in adults and adolescents on the basis of a cost-minimisation approach compared to the least costly biologic for asthma over a 1-year time frame. It was listed on 1 April 2021.
- 2.7 At its March 2022 and 2024 meeting, the PBAC recommended expanding dupilumab PFS to include paediatric population with severe atopic dermatitis (patients aged less than 12 years) and patients aged 6 to 11 years with uncontrolled severe asthma respectively. To date, the sponsor has not progressed a listing for either of these indications.
- 2.8 In its March 2022 consideration for paediatric population with severe atopic dermatitis, the PBAC was satisfied that dupilumab provides, for some patients, a significant improvement in efficacy over standard care and considered that the clinical evidence suggests the magnitude of benefit in patients aged 6-11 years is similar to that in the adult/adolescent population and the cost-effectiveness was acceptable at the same price per month as for the adult/adolescent population (Paragraph 7.1, dupilumab public summary document (PSD), March 2022).

3 Requested listing

3.1 The submission requested the following new listings, under the same conditions for which dupilumab PFS was recommended for the 6-11 years population, noting that the PFS listing for 6–11-year population has not yet been implemented. No grandfather listings were requested for dupilumab PFP. For brevity, only the new content has been included. Suggested additions are in italics. Add new medicinal product pack as follows:

Atopic dermatitis

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
DUPILUMAB					
<i>dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL pen devices</i>	<i>NEW</i>	<i>1</i>	<i>2</i>	<i>5</i>	<i>Dupixent</i>
<i>dupilumab 300 mg/2 mL injection, 2 x 2 mL pen devices</i>	<i>NEW</i>	<i>1</i>	<i>2</i>	<i>2</i>	<i>Dupixent</i>
	Administrative Advice: <i>Pharmaceutical benefits that have the form dupilumab injection 200 mg/1.14 mL, 2 x 1.14 mL syringes and pharmaceutical benefits that have the form dupilumab injection 200 mg/1.14 mL, 2 x 1.14 mL pen devices are equivalent for the purposes of substitution</i>				
	Administrative Advice: <i>Pharmaceutical benefits that have the form dupilumab injection 300 mg/2 mL, 2 x 2 mL syringes and pharmaceutical benefits that have the form dupilumab injection 300 mg/2 mL, 2 x 2 mL pen devices are equivalent for the purposes of substitution</i>				
	Category / Program: GENERAL – General Schedule (Code GE)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)				
	Indication: Chronic severe atopic dermatitis				

Uncontrolled Severe Asthma

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
DUPILUMAB					
<i>dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL pen devices</i>	<i>NEW (Public) NEW (Private)</i>	<i>1</i>	<i>2</i>	<i>7 (initial)</i>	<i>Dupixent</i>
<i>dupilumab 300 mg/2 mL injection, 2 x 2 mL pen devices</i>	<i>NEW (Public) NEW (Private)</i>	<i>1</i>	<i>2</i>	<i>3 (initial)</i>	<i>Dupixent</i>
<i>dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL pen devices</i>	<i>NEW (Public) NEW (Private)</i>	<i>1</i>	<i>2</i>	<i>5 (continuing)</i>	<i>Dupixent</i>
<i>dupilumab 300 mg/2 mL injection, 2 x 2 mL pen devices</i>	<i>NEW (Public) NEW (Private)</i>	<i>1</i>	<i>2</i>	<i>2 (continuing)</i>	<i>Dupixent</i>
	Administrative Advice:				

	Pharmaceutical benefits that have the form dupilumab injection 200 mg/1.14 mL, 2 x 1.14 mL syringes and pharmaceutical benefits that have the form dupilumab injection 200 mg/1.14 mL, 2 x 1.14 mL pen devices are equivalent for the purposes of substitution
	Administrative Advice: Pharmaceutical benefits that have the form dupilumab injection 300 mg/2 mL, 2 x 2 mL syringes and pharmaceutical benefits that have the form dupilumab injection 300 mg/2 mL, 2 x 2 mL pen devices are equivalent for the purposes of substitution
	Category / Program: Section 100 – Highly Specialised Drugs Program (Public/Private)
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
	Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)
	Indication: Uncontrolled Severe Asthma

3.2 The submission requested that equivalent strengths of dupilumab PFP and dupilumab PFS be treated as equivalent to each other for the purposes of substitution (i.e. 'a' flagged in the schedule) noting that the PBAC had previously considered under Section 101(4AACD) of the *National Health Act 1953* that dupilumab injections 200 mg/1.14 mL, 2 x 1.14 mL and 300 mg/2 mL, 2 x 2 mL syringes and dupilumab injections 200 mg/1.14 mL, 2 x 1.14 mL and 300 mg/2 mL, 2 x 2 mL pen devices, respectively, are equivalent for the purposes of substitution' (Paragraph 6.12, dupilumab PSD, November 2022). The PBAC considered that this was appropriate.

4 Comparator

4.1 The submission nominated dupilumab PFS as the main comparator for AD. The PBAC considered that this was appropriate.

4.2 The submission also nominated dupilumab PFS as the main comparator for uncontrolled severe asthma. The PBAC considered while this was an appropriate comparator, there may be other relevant alternative therapies, including other medicines that have been recommended on a cost-minimisation basis with dupilumab for this indication. The pre-PBAC response argued that PFS forms are most likely to be replaced by PFP forms and are therefore considered appropriate comparator for uncontrolled severe asthma, claiming that cost-effectiveness of dupilumab PFS had previously been established versus cost-minimisation to omalizumab.

4.3 Consistent with Section 101(3B) of the *National Health Act 1953*, if dupilumab PFP is more costly than an alternative therapy, the PBAC must be satisfied that it provides, for some patients, a significant improvement in efficacy or reduction of toxicity over the alternative therapy.

4.4 The submission stated the TGA Delegate advised that the primary difference between dupilumab PFP and dupilumab PFS are its container type, packaging and AUST R numbers. The PBAC noted the approved PI states that the pre-filled pen is for use in adult and paediatric patients aged 2 years and older. The pre-filled syringe is for use in adult and paediatric patients aged 6 months and older (Pg 7, approved dupilumab PI).

For more detail on PBAC's view, see section 6 PBAC outcome.

5 Consideration of the evidence

Sponsor hearing

5.1 There was no hearing for this item.

Consumer comments

5.2 The PBAC noted and welcomed the input from medical organisations (2) and Consumer group/organisation (2) via the Consumer Comments facility on the PBS website. The comments from Australasian Society of Clinical Immunology and Allergy (ASCIA) expressed its support for this submission, highlighting that dupilumab significantly improves the health and quality of life for patients with chronic severe atopic dermatitis (eczema) and/or uncontrolled severe asthma.

5.3 The PBAC noted input received from the National Paediatric Medicines Forum (NPMF) in support for the PBS listing of dupilumab PFP. The input outlined the effectiveness of dupilumab in treating severe uncontrolled asthma and atopic dermatitis in paediatric patients, reducing the need for excessive corticosteroids, often associated with negative long-term- adverse effects. The input further stated that NPMF developed a clinical usage criteria for dupilumab in children under 12 years to align with current evidence and that various sites have adopted these criteria for determining patient eligibility and monitoring of treatment.

5.4 The PBAC noted input from Asthma Australia stated that dupilumab provides affordable treatment option for children aged 6 - 11 years with severe eosinophilic asthma offering simpler dosing regimen, reduced dosing errors and improved adherence. The input highlights a range of benefits with dupilumab PFP including increased ease of self-administration, reduced healthcare visits and lower medical costs. However, like other biologics, dupilumab may cause adverse effects such as injection site reactions, anaphylaxis, eosinophilia and helminth infections and that proper training are essential for safe and effective use.

5.5 The PBAC also noted input from the Australasian College of Dermatologists (ACD) expressed support for the PBS listing of dupilumab PFP. The input noted that dupilumab PFP will provide a safer and more effective treatment for paediatric AD, addressing the limitations of current options which are costly and often have significant side effects.

5.6 The PBAC noted that the National Allergy Council and Allergy & Anaphylaxis Australia had also expressed its support for the dupilumab submission.

Clinical trials

5.7 The submission was based on an open-label, fixed-sequence, crossover design sub--study of the Open Label Extension (OLE) study, R668-AD-1434 to demonstrate that dupilumab PFP is non-inferior to dupilumab PFS in terms of pharmacokinetics

(PK), efficacy and safety in participants aged ≥ 2 to < 12 years with moderate to severe AD (Table 2).

- 5.8 The submission stated that while the sub-study focussed exclusively on children with AD, the pharmacokinetic profile of dupilumab is expected to be consistent across different indications with similar underlying physiology. As such, it is likely for dupilumab PFP to produce comparable health outcomes as AD in paediatric patients with uncontrolled severe asthma.
- 5.9 The TGA Clinical Evaluation Report (CER) stated the data from the sub-study, overall suggested that there is no difference in the PK profiles between dupilumab PFP and dupilumab PFS. It further stated that no safety concerns were identified and that no participants exhibited a treatment emergent, or treatment boosted anti-drug antibody response during treatment with dupilumab PFP (dupilumab CER).
- 5.10 The TGA CER stated that a supplemental Human Factors Validation study (sHFVS) which assessed administration of dupilumab PFP for children aged 2 to < 12 years with asthma and/or atopic dermatitis (AD) by caregivers or healthcare professionals (HCPs) demonstrated that the revised Instructions for Use (IFU) support the safe and effective use of dupilumab PFP by lay caregivers (dupilumab CER).

Table 2: Study presented in the submission

Study ID	Publication title	Publication
R668-AD-1434 NCT02612454	An Open-Label Extension Study to Assess the Long-Term Safety and Efficacy of Dupilumab in Patients ≥ 6 Months to < 18 Years of Age with Atopic Dermatitis.	18 November 2019

Source: Clinical study report attached to submission.

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

Clinical claim

- 5.12 The submission claimed non-inferior comparative effectiveness and safety of dupilumab PFP compared with dupilumab PFS.
- 5.13 The PBAC considered that the claim of non-inferior comparative effectiveness and safety was reasonable.

Economic analysis

- 5.14 The submission presented a cost-minimisation approach of dupilumab PFP compared with dupilumab PFS assuming there will be no material differences in administration complexity or completeness, setting of care, treatment uptake, compliance or adherence, or use of other healthcare resources arising following the listing of dupilumab PFP.
- 5.15 The submission estimated the equi-effective doses to be:
- Dupilumab PFP 200 mg in 1.14 mL once every 2 weeks (Q2W) = Dupilumab PFS 200 mg in 1.14 mL Q2W
 - Dupilumab PFP 300 mg in 2.0 mL Q2W = Dupilumab PFS 300 mg in 2.0 mL Q2W

- Dupilumab PFP 300 mg in 2.0 mL every 4 weeks (Q4W) = Dupilumab PFS 300 mg in 2.0 mL Q4W.

5.16 As a Category 4 submission, the economic analysis has not been independently evaluated.

Estimated PBS usage and financial implications

5.17 The submission adopted a market share approach to estimate the utilisation and financial impact of listing dupilumab PFP for AD and uncontrolled severe asthma. The submission determined these estimates using the PBS data of medicines whose costs are identical to dupilumab PFP and the currently listed dupilumab PFS as of 1 November 2024 (i.e. the current published prices were used as provisional values for the anticipated reweighted approved ex-manufacturer price (AEMP)).

5.18 The submission requested the same effective and published AEMP for dupilumab PFP as dupilumab PFS, noting that prices may be subject to future modifications driven by the weighted pricing to account for the 2 and 4 weekly dosing schedules.

5.19 The submission made the following assumptions to estimate PBS usage and financial implication:

- The substitution rates would gradually increase but are unlikely to reach 100% due to the continued preference for dupilumab PFS by some patients.
- In the first year of listing, the PFP devices will replace $\frac{1}{2}$ % of the predicted total utilisation of dupilumab for both AD and uncontrolled severe asthma, increasing by $\frac{1}{2}$ % per year to a maximum of $\frac{1}{2}$ % in year 6.
- The predicted utilisation of dupilumab was by indication and restriction. The submission stated that there were insufficient rows in the utilisation and cost model workbook to allow for analysis by treatment phase (initiating vs continuing) for either AD or uncontrolled severe asthma indications. The submission stated that as the listing of dupilumab PFP is estimated to be cost-neutral, the stratification of utilisation into treatment phase will have limited impact on the listing. The submission further noted that, if recommended, the Sponsor will collaborate closely with the PBS restrictions team to ensure accurate treatment phase representation in PBS restriction.

5.20 Dupilumab PFP would substitute for use of dupilumab PFS on a 1:1 basis for both AD and uncontrolled severe asthma indications. As such, the submission estimated the requested listing of dupilumab PFP to be cost neutral to the PBS/RPBS.

5.21 Table 3 presents the estimated extent of use, cost and net financial implications of listing dupilumab PFP to the PBS/RPBS. Although, the submission stated that there would be no expected implication for Services Australia, the financial impact will be determined by that agency as part of the post PBAC process.

- 5.22 The submission stated that there would be no additional cost to Medicare Benefits Schedule (MBS) as patients would be offered the option to transition between dupilumab PFP and dupilumab PFS during their next routine specialist visit.
- 5.23 The submission estimated the net financial implication of listing dupilumab PFP to the PBS/RPBS to be nil over six years, noting no RPBS listing for paediatric patients.
- 5.24 The estimation of nil financial impact assumes implementation of recommendations from the March 2022 and 2024 meetings to expand subsidy for dupilumab PFS to include paediatric population with severe AD (patients aged less than 12 years) and patients aged 6 to 11 years with uncontrolled severe asthma.

Table 3: Estimated use and financial implications for AD and uncontrolled severe asthma

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use						
Number of scripts for AD and asthma	1	1	2	2	2	2
Estimated net financial implications						
Cost to PBS	\$3	\$4	\$4	\$4	\$5	\$5
Changed listing	-\$6	-\$6	-\$6	-\$6	-\$6	-\$6
Net cost to PBS	\$0	\$0	\$0	\$0	\$0	\$0

Source: Sheet 3a, 3b and 5 of financial model spreadsheet.

Note: No RPBS listing for paediatric cohort of patients

Abbreviations: AD = Atopic dermatitis; PBS = Pharmaceutical Benefits Scheme.

The redacted values correspond to the following ranges:

¹ 500 to < 5,000

² 5,000 to < 10,000

³ \$0 to < \$10 million

⁴ \$10 million to < \$20 million

⁵ \$20 million to < \$30 million

⁶ net cost saving

Quality use of medicine

- 5.25 The submission provided the approved IFU documents for dupilumab PFP which outlines the relevant information necessary for the appropriate use of dupilumab PFP by patients, caregivers and HCPs.

Risk-sharing arrangements

- 5.26 The submission assumed that dupilumab PFP will be subject to the same Deed arrangements that would apply for paediatric AD and uncontrolled severe asthma. The PBAC noted that the sponsor has not progressed a listing for either of these indications to date.

6 PBAC Outcome

- 6.1 The PBAC recommended the General Schedule Authority Required listing of two new forms of dupilumab, 200 mg in 1.14 mL and 300 mg in 2 mL single dose pre-filled pen (PFP) for the treatment of severe atopic dermatitis (AD) in patients aged less than 12 years on a cost minimisation basis to dupilumab PFS. The PBAC further recommended the Section 100 (Highly Specialised Drugs Program) Authority Required

(Written) listing of dupilumab PFP for the treatment of uncontrolled severe asthma in patients aged 6 to 11 years. The PBAC's recommendation for listing was based on, among other matters, its assessment that dupilumab PFP would be cost-effective if it were cost-minimised to the lowest cost alternative therapy for uncontrolled severe asthma.

- 6.2 The PBAC considered the following equi-effective doses to be appropriate:
- 200 Dupilumab PFP = 200 Dupilumab PFS
 - 300 Dupilumab PFP = 300 Dupilumab PFS
- 6.3 The PBAC considered that the nominated comparator, dupilumab PFS was an appropriate comparator for AD and uncontrolled severe asthma. However, the PBAC noted that other relevant comparators could include omalizumab for uncontrolled severe asthma. The PBAC noted that the sponsor claimed in its pre-PBAC response that dupilumab PFS is the appropriate comparator for uncontrolled severe asthma. The PBAC recalled its March 2024 consideration of dupilumab PFS for uncontrolled severe asthma, that the recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of dupilumab would be acceptable if it were cost-minimised against omalizumab.
- 6.4 The PBAC recalled that in November 2022, it had considered under Section 101(4AACD) of the *National Health Act 1953* that dupilumab injections 200 mg/1.14 mL, 2 x 1.14 mL and 300 mg/2 mL, 2 x 2 mL syringes and dupilumab injections 200 mg/1.14 mL, 2 x 1.14 mL and 300 mg/2 mL, 2 x 2 mL pen devices, respectively, are equivalent for the purposes of substitution in the Schedule of Pharmaceutical Benefits.
- 6.5 The PBAC noted the submission estimated a nil net financial implication to the PBS/RPBS based on the assumption that dupilumab PFP will be listed on the PBS at the same price as dupilumab PFS and that dupilumab PFP is expected to directly substitute dupilumab PFS, unit for unit for both AD and uncontrolled severe asthma indications. The PBAC noted that as dupilumab PFS has not yet been listed for paediatric population on the PBS, prices for these indications had not been agreed. The PBAC considered that the listing of dupilumab PFP is unlikely to increase the market and therefore considered the listing would not result in an increase cost to PBS/RPBS. With regard to the paediatric population, the PBAC considered the listing of dupilumab PFP would not be expected to change the financial impact that was previously recommended for dupilumab PFS in March 2024, provided it listed under the same circumstances as was recommended for dupilumab PFS.
- 6.6 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because dupilumab PFP is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over dupilumab PFS, or not 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.

- 6.7 The PBAC noted that this submission is not eligible for an Independent Review because it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

- 7.1 Add new medicinal product pack as follows:

Atopic dermatitis

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
DUPILUMAB					
<i>dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL pen devices</i>	NEW	1	2	5	Dupixent
<i>dupilumab 300 mg/2 mL injection, 2 x 2 mL pen devices</i>	NEW	1	2	2	Dupixent
	Administrative Advice: <i>Pharmaceutical benefits that have the form dupilumab injection 200 mg/1.14 mL, 2 x 1.14 mL syringes and pharmaceutical benefits that have the form dupilumab injection 200 mg/1.14 mL, 2 x 1.14 mL pen devices are equivalent for the purposes of substitution</i>				
	Administrative Advice: <i>Pharmaceutical benefits that have the form dupilumab injection 300 mg/2 mL, 2 x 2 mL syringes and pharmaceutical benefits that have the form dupilumab injection 300 mg/2 mL, 2 x 2 mL pen devices are equivalent for the purposes of substitution</i>				
	Category / Program: GENERAL – General Schedule (Code GE)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)				
	Indication: Chronic severe atopic dermatitis				

Uncontrolled Severe Asthma

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
DUPILUMAB					
<i>dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL pen devices</i>	NEW (Public) NEW (Private)	1	2	7 (initial)	Dupixent
<i>dupilumab 300 mg/2 mL injection, 2 x 2 mL pen devices</i>	NEW (Public) NEW (Private)	1	2	3 (initial)	Dupixent
<i>dupilumab 200 mg/1.14 mL injection, 2 x 1.14 mL pen devices</i>	NEW (Public) NEW (Private)	1	2	5 (continuing)	Dupixent
<i>dupilumab 300 mg/2 mL injection, 2 x 2 mL pen devices</i>	NEW (Public) NEW (Private)	1	2	2 (continuing)	Dupixent
	Administrative Advice:				

	<p><i>Pharmaceutical benefits that have the form dupilumab injection 200 mg/1.14 mL, 2 x 1.14 mL syringes and pharmaceutical benefits that have the form dupilumab injection 200 mg/1.14 mL, 2 x 1.14 mL pen devices are equivalent for the purposes of substitution</i></p>
	<p>Administrative Advice: <i>Pharmaceutical benefits that have the form dupilumab injection 300 mg/2 mL, 2 x 2 mL syringes and pharmaceutical benefits that have the form dupilumab injection 300 mg/2 mL, 2 x 2 mL pen devices are equivalent for the purposes of substitution</i></p>
	<p>Category / Program: Section 100 – Highly Specialised Drugs Program (Public/Private)</p>
	<p>Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners</p>
	<p>Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)</p>
	<p>Indication: Uncontrolled Severe Asthma</p>

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

8 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.

9 Sponsor's Comment

The sponsor had no comment.