

**11.09 DUPILUMAB,
Injection 200 mg in 1.14 mL single dose
pre-filled syringe,
Injection 300 mg in 2 mL single dose
pre-filled syringe,
Dupixent[®],
SANOFI-AVENTIS AUSTRALIA PTY LTD**

1 Purpose

- 1.1 The sponsor of dupilumab (Dupixent[®]), Sanofi-Aventis, has submitted a request to delist dupilumab from the PBS for the treatment of severe atopic dermatitis (AD).
- 1.2 The delist submission requests the PBAC to reconsider its November 2023 advice in relation to a revised risk sharing arrangement (RSA), and outlines concerns regarding the advice in relation to the cost-effective ICER and associated magnitude of price reduction. The sponsor states that in the absence of acceptance of its proposal, it is requesting that dupilumab be delisted from the PBS, for the severe AD indication only, from 1 December 2024.
- 1.3 The sponsor's proposal includes:
- Price reduction of |% (effective ex-manufacturer)
 - Estimates for Year 4 and 5 of the Deed extrapolated following a linear trend
 - Proposed caps based at |% below the forecast estimates using the proposed price (to achieve a |% reduction in cost overall)
- 1.4 The sponsor provided the following further information in relation to its request:
- Supplementary information for application to delist Dupixent (dupilumab) for Severe Atopic Dermatitis for patients aged 12 years and older from the PBS (provided 11 June 2024)
 - Additional proposal containing supplementary offer |

2 Background

- 2.1 In November 2023, the PBAC considered the cost-effectiveness of PBS-listed drugs (dupilumab and upadacitinib) for treatment of severe AD. This was in the context of the request to increase the financial caps in place for the agreed RSA.

November 2023 PBAC advice

- 2.2 The PBAC considered an ICER of \$15,000 to < \$25,000/QALY would be cost effective in the current, much larger than predicted, population. The PBAC noted a DPMQ of \$1 (35% reduction from the current DPMQ) would be required to achieve an ICER of \$15,000 to < \$25,000/QALY. However, the PBAC considered the ICER to be underestimated. Overall, the PBAC considered dupilumab would likely be cost-effective with a price reduction in the order of 50% (paragraph 6.14, Review of cost-effectiveness of drugs for atopic dermatitis: Dupilumab and Upadacitinib (item 4.02) Public Summary Document [PSD] November 2023 PBAC meeting).
- 2.3 The PBAC further noted both sponsors expected the expenditure to continue to increase over the remaining Deed period. However, the PBAC considered that there was no clear basis for forecasting estimated utilisation for the remaining 2 years of the Deed (and beyond) as the number of initiating patients would be expected to decline in the future as the market becomes saturated, but it is not known over what time period this would occur and hence when the overall market would stabilise (paragraph 6.7, Review of cost-effectiveness of drugs for atopic dermatitis PSD November 2023 PBAC meeting).
- 2.4 Upadacitinib was recommended for listing on the PBS for severe AD for patients aged 12 years and older on a cost- minimisation basis against dupilumab. It was PBS-listed on 1 February 2022. Lebrikizumab was recommended for the same indication as dupilumab at the March 2024 PBAC meeting, but has not yet progressed to a listing.
- 2.5 At its March 2022 meeting the PBAC recommended extending the listing of dupilumab to patients aged less than 12 years with severe AD. However, the sponsor has chosen not to proceed with the listing to date.
- 2.6 The sponsor states that approximately 10,000 to < 20,000 patients are currently receiving subsidised access to dupilumab for the treatment of AD, who would need to be prescribed an alternative treatment if delisted.

3 Current situation

- 3.1 The table below outlines the current subsidisation caps for severe AD, and actual Commonwealth payment over the first 3 years of the RSA. A 1% rebate applies for use exceeding the caps.

Table 1: Current RSA caps

	Y1 (Mar 2021- Feb 2022)	Y2 (Mar 2022- Feb 2023)	Y3 (Mar 2023- Feb 2024)	Y4 (Mar 2024- Feb 2025)	Y5 (Mar 2025- Feb 2026)
Current caps ¹	\$1	\$1	\$1	\$1	\$1
Actual Commonwealth Payment	\$1	\$1	\$ ²	-	-

¹Increased February 2022 upon listing of upadacitinib, and from Year 3 onwards following July 2023 PBAC advice for hand/face population

²Current estimate, not yet invoiced

- 3.2 Following the November 2023 PBAC advice, the sponsor submitted a proposal to the Department to increase the RSA caps.

Table 2: Summary of the November 2023 PBAC consideration and current proposal regarding price

November 2023 sponsor proposal	November 2023 PBAC advice	Current sponsor proposal (dated March 2024)
\$█ (█% reduction from current price of \$█ per pack)	<p>The PBAC noted when applied in the economic model presented in the November 2019 submission, reduced the ICER from \$█/QALY to \$30,000/QALY. The PBAC considered dupilumab was not cost-effective at the price proposed because the potential use in less severe disease and higher continuation rates were not accounted for, and the ICER remained too high.</p> <p>The PBAC noted a DPMQ of \$█ (35% reduction from the current DPMQ) would be required to achieve an ICER of \$15,000/QALY. However as outlined in paragraph 6.13, the PBAC considered the ICER to be underestimated. Overall, the PBAC considered dupilumab would likely be cost-effective with a price reduction in the order of 50%.</p>	<p>\$█ (unchanged from November 2023)</p> <p>The sponsor proposes that a █% reduction in cost would be achieved in conjunction with caps set at █% below its expenditure forecast using the proposed price.</p>

The redacted values correspond to the following ranges:

¹ \$45,000 to < \$55,000

3.3 The following table outlines the sponsor’s proposed subsidisation caps (only for remainder of Deed period, i.e. up to February 2026).

Table 3: Summary of the sponsor’s proposed subsidisation caps

	Y3 (Mar 2023-Feb 2024)	Y4 (Mar 2024-Feb 2025)	Y5 (Mar 2025-Feb 2026)
Current caps	\$█	\$█	\$█
Actual Commonwealth Payment	\$█	-	-
Sponsor projection of Commonwealth Payment (at current price)		\$█	\$█
Sponsor proposed caps (█% below projection)		\$█	\$█
November 2023 Pre-PBAC proposed caps	\$█	\$█	\$█

3.4 The Department did not accept the sponsor’s proposal as:

- The magnitude of the price reduction (█%), which had already been considered by PBAC in November 2023, was not consistent with the PBAC advice for a price reduction in the order of 50%.
- Noting that the proposal claims that the caps are based below the level of estimated utilisation in order to achieve a █% reduction, the Department considered that this mechanism to achieve a price reduction is not consistent with the advice of the PBAC, in the context that there is already a cap arrangement in place that is resulting in reimbursements for use above the caps, and renegotiation of the Deed should be in the context of an appropriate price reduction. Further, the █% reduction is not aligned with a price reduction in the order of 50%.
- The forecast informing the requested caps follows a linear trend. In the context of the PBAC advice that there was no clear basis for forecasting estimated utilisation for the remaining 2 years of the Deed (and beyond) as the number of initiating

patients would be expected to decline in the future as the market becomes saturated, the department’s view was that it would be more appropriate to apply more conservative assumptions regarding the growth rate for future years.

- 3.5 The Department provided the following counter-proposal to the sponsor, with cap forecasts based on more conservative assumptions regarding extrapolation (log model based on annual actual expenditure over the first three years of the Deed).

Table 4: Summary of the Department’s proposed subsidisation caps

	Y4 (Mar 2024-Feb 2025)	Y5 (Mar 2025-Feb 2026)	Mar 2026-Feb 2027	Mar 2027-Feb 2028	Mar 2028-Feb 2029
Current caps	\$	\$	-	-	-
Sponsor proposed caps (█% below projection)	\$	\$	-	-	-
Department projection of Commonwealth Payment (at current price)	\$	\$	\$	\$	\$
Department proposed caps (Option 1 with 50% price reduction)	\$	\$	\$	\$	\$

- 3.6 The Department also provided a second option for consideration, should the sponsor be unable to offer a further unit price reduction, with an increase of approximately \$| million each year to the current caps. This reflected on average, an increase to caps proportionate to the reduction the sponsor offered vs the PBAC recommendation (█%/50%).

- 3.7 The sponsor did not accept either of the options presented and stated that the Department’s methodology established caps substantially below predicted utilisation. The sponsor claims that the utilisation estimates provided in its proposal are supported by both the results of validation vs. the best fit extrapolation and comparisons to real world launch data from other markets and as such, are the most plausible basis on which to forecast the remaining two years of the RSA.

4 Consideration of the evidence

Consumer comments

- 4.1 The PBAC and Department received correspondence regarding the potential delisting of dupilumab from the PBS, expressing concern if dupilumab was no longer able to be accessed via the PBS. A total of twelve pieces of correspondence was received, from individual clinicians (9), the Australasian College of Dermatologists, and the organisations Allergy & Anaphylaxis Australia and Eczema Support Australia (on behalf of patients, their families, and clinicians and other organisations).
- 4.2 Correspondence noted the challenges for patients with atopic dermatitis and difficulties with its management, including adverse effects associated with other treatment options. Correspondence also noted the benefits dupilumab has provided to many patients, including physical, psychological and social benefits, and its

increased effectiveness and improved safety profile compared to other therapeutic options.

- 4.3 Some correspondence outlined that upadacitinib is not a suitable alternative for all patients, citing differences in safety, potential drug interactions and high rate of loss of efficacy with upadacitinib.

Economic analysis

- 4.4 The sponsor claims that the quantum of price reduction recommended by the PBAC in November 2023 (50%) is higher than the worst-case analysis generated by the economic model, used in combination with an inappropriately low ICER threshold (\$15,000 to < \$25,000/QALY).
- 4.5 The PBAC conclusion of a 50% reduction in price for dupilumab to be considered cost-effective was based on accounting for (i) the higher continuation rate, (ii) the potential use in patients with less severe AD, and (iii) the current expenditure being higher than forecasted at the time the listing was recommended (paragraph 6.5, Review of cost-effectiveness of drugs for atopic dermatitis PSD, November 2023 PBAC meeting).
- 4.6 The 'worst-case analysis' referred to by the sponsor is the analysis which incorporates the additional cost, but not the additional benefit, for the additional 18.6% of patients continuing dupilumab at week 16 versus that expected based on the clinical trial data. The sponsor noted this analysis was acknowledged as potentially conservative by the PBAC, and that it is predicated on the assumption that the benefit derived for the additional continuing patients would be reduced. The sponsor considers no justification was provided for this assumption and that it is unclear why the benefit for patients with moderate disease would be less than that for patients with severe disease.
- 4.7 The PBAC previously noted the severity of AD can fluctuate over time and hence patients with predominately moderate disease may access treatment during a period where their disease is classified as severe, and then remain on treatment (paragraph 6.3, Review of cost-effectiveness of drugs for atopic dermatitis PSD, November 2023 PBAC meeting). The proposal submitted by AbbVie for consideration at the November 2023 PBAC meeting included EQ-5D utility data which showed a smaller utility gain for patients with moderate (difference of 0.16) versus severe (difference of 0.23) disease (Table 5, Review of cost-effectiveness of drugs for atopic dermatitis PSD, November 2023 PBAC meeting).
- 4.8 The sponsor strongly disagreed that an ICER of \$15,000 - <\$25,000/QALY is sufficient to represent the additional clinical benefit of dupilumab over standard of care (SoC). The sponsor considered the value of the clinical benefit provided by dupilumab over SoC is reflected by the PBAC's decision to recommend dupilumab for listing on the basis of an ICER of \$45,000 to < \$55,000/QALY. The sponsor argued that the cost-effectiveness has been conflated with the size of the treated population, and that the acceptance of a particular ICER as cost-effective is related to the level of uncertainty

associated with the generation of that ICER, and the size of the treated population does not change the level of uncertainty present. The PBAC noted the size of the treated population does change the extent of uncertainty as well as the level of uncertainty that is acceptable. Examples of factors increasing the uncertainty of the cost-effectiveness of dupilumab include potential use in patients with fluctuating and less severe disease on average, and use in a broader population than for which phototherapy is used, noting that costs for phototherapy were included as an offset in the economic model.

- 4.9 The sponsor stated that when the proposed price reduction (█%) and reduction in financial caps (█%) are combined, that there will be a █% reduction in the maximum potential cost to government in years 4 and 5 of the deed. The sponsor calculated that incorporating this █% reduction into the economic model results in an ICER of \$15,000 to < \$25,000/QALY when not adjusting for additional patients continuing therapy, \$35,000 to < \$45,000/QALY when incorporating the cost of additional patients continuing but no benefit, and \$15,000 to < \$25,000/QALY when incorporating the cost of additional patients continuing and assuming the same benefit for all continuing patients.

Estimated PBS usage & financial implications

- 4.10 The sponsor stated it has used a bottom-up patient model based on actual patient numbers and monthly data to inform its script forecast.

Figure 1: Sponsor forecast of packs for Year 4 & 5 of the RSA



Source: Sanofi's Forecast model_Dupilumab AD

- 4.11 The sponsor’s forecast results in a Year 4 figure which represents growth of ██████% from the actual PBS expenditure in Year 3, and █% increase from the proposed Year 4 to Year 5 cap (see Table 3).
- 4.12 This represents an additional \$100 million to < \$200 million in Year 4 and \$100 million to < \$200 million in Year 5 to Commonwealth expenditure.
- 4.13 Any new arrangement should provide a 6-year forecast to cover the forward estimates period.
- 4.14 Following are the results of utilisation analyses of dupilumab undertaken by the DUSC Secretariat. In 2023, there were 10,000 to < 20,000 patients supplied dupilumab for severe atopic dermatitis. The table below presents utilisation of dupilumab for severe atopic dermatitis by listing year.

Table 5: Utilisation of dupilumab for severe atopic dermatitis by listing year

	List Year 1 (Mar 2021 - Feb 2022)	List Year 2 (Mar 2022 - Feb 2023)	List Year 3 (Mar 2023 - Feb 2024)
Incident (new) patients	█ ¹	█ ¹	█ ¹
Prevalent (all treated) patients	█ ¹	█ ²	█ ²
PBS quantity dispensed	█ ³	█ ⁴	█ ⁵
Number of prescriptions supplied	█ ⁶	█ ³	█ ³

Source: Data extracted from the PBS database maintained by Department of Health and Aged Care, processed by Services Australia were used for the analyses. The PBS item codes used for the data extraction included 12291X and 12292Y. The data analysis was undertaken on 6 June 2024.

The redacted values correspond to the following ranges:

¹ 5,000 to < 10,000

² 10,000 to < 20,000

³ 100,000 to < 200,000

⁴ 200,000 to < 300,000⁵ 300,000 to < 400,000

⁶ 60,000 to < 70,000

- 4.15 The utilisation of dupilumab and upadacitinib for severe atopic dermatitis was considered by DUSC at its June 2024 meeting. To consider the size of the potential untreated eligible population, the following forecast was produced (Table 6). The forecast was based on the assumption that the prevalent treated population within the severe atopic dermatitis market does not stabilise.

Table 6: Forecasts of the eligible and PBS treatment populations for severe atopic dermatitis

Parameter	Model step	Value applied and source	Mar 24 - Feb 25	Mar 25 - Feb 26	Mar 26 - Feb 27	Mar 27 - Feb 28	Mar 28 - Feb 29
General population - all ages	[1]	ABS, population projections - medium series	26,971,766	27,395,011	27,805,684	28,201,094	28,581,272
Prevalence of severe AD	[2] = [1] x 0.0045	45 per 10,000. Source: Table 19, Dupilumab PSD March 2020 PBAC meeting.	121,373	123,278	125,126	126,905	128,616
Proportion of severe AD patients with EASI \geq 20	[3] = [2] x 0.95	95%. Source: Table 19, Dupilumab PSD March 2020 PBAC meeting	115,304	117,114	118,869	120,560	122,185
Proportion of patients on TCS therapy with uncontrolled AD	[4] = [3] x 0.68	68%. Source: Table 19, Dupilumab PSD March 2020 PBAC meeting	78,407	79,637	80,831	81,981	83,086
Projected eligible population	[5] = [4]		78,407	79,637	80,831	81,981	83,086
Projected PBS treated population*	[6]	PBS data, prevalent patient counts supplied dupilumab or upadacitinib. Linear forecast	31,253	38,850	46,447	54,044	61,641
Estimate eligible patients not accessing PBS biologic	[7] = [5] - [6]		47,154	40,788	34,384	27,937	21,445

Note: Modelling parameters for the eligible population are based on assumptions accepted by the PBAC for the recommendations of dupilumab and upadacitinib. Refer to Public Summary Document for upadacitinib July 2021 Table 16. Accessed at: <https://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2021-07/upadacitinib-tablet-15-mg-tablet-30-mg-rinvoq>.

*The treated population was based on PBS data extracted based on the date of supply for the following item codes: '12291X','12292Y','12827D','12828E','12829F','12831H','12835M','12836N'. Actual unique counts of prevalent patients were calculated for Mar 21 - Feb 22, Mar 22 - Feb 23 and Mar 23 - Feb 24. The FORECAST function was used to project the number of prevalent patients based on the actual patient counts.

4.16 The Secretariat compiled expected financial implications (at current price of dupilumab) assuming a linear forecast and a forecast assuming the market matures from Year 4 (see Table 7 & Table 8 below).

Table 7: Secretariat compiled utilisation estimates based on linear forecast

	2024	2025	2026	2027	2028	2029
Dupilumab						
Total Treated Patients ¹	3	3	4	5	5	6
Initiating Patients	7	7	7	7	8	8
Continuing Patients	7	8	8	3	3	4
Initiating Scripts	6	9	10	11	11	11
Continuing Scripts	11	11	11	11	12	12
Upadacitinib						
Total Treated Patients ¹	13	13	7	7	7	7
Initiating Patients	14	14	14	14	14	13
Continuing Patients	13	13	13	13	7	7
Initiating Scripts ²	7	7	7	7	8	8
Continuing Scripts ²	3	3	4	5	6	6
Total Scripts (Dupilumab + Upadacitinib)	12	12	15	15	16	16
Estimated financial implications of Dupilumab and Upadacitinib (cost to PBS/RPBS less co-payment)						
Net cost to PBS/RPBS	\$ ¹⁷	\$ ¹⁷	\$ ¹⁸	\$ ¹⁸	\$ ¹⁹	\$ ¹⁹

¹The treated population was based on PBS data extracted based on the date of supply for the following item codes: '12291X','12292Y','12827D','12828E','12829F','12831H','12835M','12836N'. The FORECAST function was used to project the number of prevalent patients based on the actual patient counts.

² The first supply for a given treatment phase (initiating or continuing) was identified for each patient. The number of scripts and time from the initial supply was calculated for the given treatment phase. Supplies after 365 days were removed and script counts retained for each patient for up to 12 months. The last patient record for a given treatment phase was retained. The mean script count was then calculated.

The redacted values correspond to the following ranges:

³ 30,000 to < 40,000

⁴ 40,000 to < 50,000

⁵ 50,000 to < 60,000

⁶ 60,000 to < 70,000

⁷ 10,000 to < 20,000

⁸ 20,000 to < 30,000

⁹ 70,000 to < 80,000

¹⁰ 90,000 to < 100,000

¹¹ 100,000 to < 200,000

¹² 200,000 to < 300,000

¹³ 5,000 to < 10,000

¹⁴ 500 to < 5,000

¹⁵ 300,000 to < 400,000

¹⁶ 400,000 to < 500,000

¹⁷ \$200 million to < \$300 million

¹⁸ \$300 million to < \$400 million

¹⁹ \$400 million to < \$500 million

Table 8: Secretariat compiled utilisation estimates based on forecast assuming market matures from Year 4

	2024	2025	2026	2027	2028	2029
Dupilumab						
Total Treated Patients ¹	3	3	4	5	5	5
Initiating Patients	6	6	6	6	7	7
Continuing Patients	6	7	7	3	3	3
Initiating Scripts	8	9	10	11	11	11
Continuing Scripts	11	11	11	11	12	12
Upadacitinib						
Total Treated Patients ¹	13	13	6	6	6	6
Initiating Patients	14	14	14	14	14	14
Continuing Patients	13	13	13	13	13	6
Initiating Scripts ²	6	6	6	6	6	6
Continuing Scripts ²	3	3	4	5	5	8
Total Scripts (Dupilumab + Upadacitinib)	12	12	15	15	15	16
Estimated financial implications of Dupilumab and Upadacitinib (cost to PBS/RPBS less co-payment)						
Net cost to PBS/RPBS	\$17	\$17	\$18	\$18	\$18	\$18
Net cost to PBS/RPBS (with █% reduction in cost)	\$19	\$19	\$17	\$17	\$17	\$17

¹The treated population was based on PBS data extracted based on the date of supply for the following item codes: '12291X','12292Y','12827D','12828E','12829F','12831H','12835M','12836N'. The FORECAST function was used to project the number of prevalent patients based on the actual patient counts in the first 3 years. The annual growth rate was adjusted in years 2027, 2028 and 2029 with a reduction of 5% assuming that the market would begin to stabilise during this time.

²The first supply for a given treatment phase (initiating or continuing) was identified for each patient. The number of scripts and time from the initial supply was calculated for the given treatment phase. Supplies after 365 days were removed and script counts retained for each patient for up to 12 months. The last patient record for a given treatment phase was retained. The mean script count was then calculated.

The redacted values correspond to the following ranges:

- ³ 30,000 to < 40,000
- ⁴ 40,000 to < 50,000
- ⁵ 50,000 to < 60,000
- ⁶ 10,000 to < 20,000
- ⁷ 20,000 to < 30,000
- ⁸ 60,000 to < 70,000
- ⁹ 70,000 to < 80,000
- ¹⁰ 90,000 to < 100,000
- ¹¹ 100,000 to < 200,000
- ¹² 200,000 to < 300,000
- ¹³ 5,000 to < 10,000
- ¹⁴ 500 to < 5,000
- ¹⁵ 300,000 to < 400,000
- ¹⁶ 400,000 to < 500,000
- ¹⁷ \$200 million to < \$300 million
- ¹⁸ \$300 million to < \$400 million
- ¹⁹ \$100 million to < \$200 million

5 PBAC Outcome

5.1 The PBAC provided further advice regarding the cost-effectiveness, estimated financial implications, and Risk Sharing Arrangement (RSA) for dupilumab for the treatment of severe atopic dermatitis in patients aged 12 years and older, in the context of the sponsor's request to otherwise delist dupilumab for this indication from the PBS. In providing this advice, the PBAC considered the necessity to ensure continued access to dupilumab, acknowledging that dupilumab was an important

treatment option for patients with severe atopic dermatitis, and its removal from the PBS would result in an unmet clinical need.

- 5.2 The PBAC received correspondence from a number of individual clinicians as well as clinician and patient groups who had been notified by the sponsor of its delist request. The PBAC noted the strong support for continued listing of dupilumab and the testimonials of the physical, psychological and social benefits realised for patients who have accessed the medicine through the PBS listing. The PBAC also noted the concern from these stakeholders of a lack of suitable alternative treatments, and that upadacitinib, which is also PBS-listed for severe atopic dermatitis in patients 12 years and older, is not a suitable alternative for all patients, with perceived differences in safety, drug interactions and high rate of loss of efficacy.
- 5.3 The PBAC recalled in July 2021 it had considered there was a possible minor added benefit for upadacitinib compared with dupilumab due to a faster onset of response, but that this benefit was offset by an increase in treatment related adverse events (paragraph 7.11, Upadacitinib PSD, July 2021 PBAC meeting).
- 5.4 The PBAC noted the concerns outlined in the submission regarding the Committee's November 2023 consideration of the appropriate ICER threshold in the significantly larger than originally projected population, and the modifications to the assumptions in the economic analysis underpinning the 50% price reduction that PBAC considered appropriate (refer para 4.4 to 4.9). The PBAC considered its November 2023 advice in regard to reassessing the acceptable ICER was appropriate, and noted that the size of the treated population is an important factor in assessing the extent of uncertainty as well as the level of uncertainty that is acceptable.
- 5.5 The PBAC noted the submission's claims that a [REDACTED] % price reduction in the economic model results in an ICER of \$15,000 to < \$25,000/QALY where the cost of additional patients continuing therapy are incorporated and the same benefit is assumed for all continuing patients. The PBAC noted that this analysis is informed by highly optimistic assumptions, however in the context of the delist request, considered this represented the minimum level of price reduction that should be required to adjust the RSA caps in line with actual utilisation.
- 5.6 The PBAC noted the June 2024 DUSC advice, which reviewed more recent utilisation data available following the November 2023 PBAC meeting. DUSC indicated that the severe atopic dermatitis market may not reach saturation for some time, noting a gap between disease prevalence and treated prevalence. The PBAC agreed with the DUSC's view that a forecast of expected utilisation closely following a linear trend over the remaining Year 4 and Year 5 of the current RSA, was not unreasonable.
- 5.7 The PBAC noted the Department's advice that changes to the financial impact of the dupilumab listing would need to be forecast for the forward estimates period. The PBAC considered that a linear trend for 3 years (from Year 4 of the RSA) and then maturation from the 4th year (i.e. from March 2027) onwards would be a reasonable

basis for the utilisation estimates and the Department modelled forecast at Table 8 would be an appropriate baseline.

- 5.8 The PBAC noted the sponsor's proposal to use a combination of a unit price reduction of 1% and the RSA caps to achieve a 1% total reduction in cost. The PBAC considered that under the current arrangement of 1% reimbursement above caps, and where a further reduction in the price of dupilumab was not possible, the RSA caps may potentially be used to ensure the total annual cost reflects the estimated cost to PBS with the equivalent reduction in price required, and where the Commonwealth could ensure that the appropriate ICER is achieved regardless of utilisation, i.e. to manage a scenario in which actual expenditure is lower than estimated.
- 5.9 The PBAC noted that the sponsor had subsequently provided a conditional offer to the Department dated 9 July 2024, claiming to provide offsets of approximately \$11 per year 11. The PBAC considered that it was a matter for Government to consider this proposal in the context of managing the total budgetary impact of an increase to the dupilumab RSA caps, however noted that there was inherent uncertainty associated with the magnitude of the saving outlined in the sponsor's proposal, 1. Overall, the PBAC considered that even if the optimistic assumptions of the offset were accepted, it represented a very modest save in contrast to the magnitude of the cost of the dupilumab RSA caps (over \$1 billion over 5 years).
- 5.10 The PBAC considered that any increase to the RSA caps based on this advice was only applicable in the case where a PBS listing was maintained for at least one monoclonal antibody inhibitor (i.e. dupilumab or lebrikizumab (not yet PBS-listed)), noting that upadacitinib appears inferior in terms of safety versus dupilumab (see paragraph 5.3), the consistent view from the stakeholder comments received that upadacitinib would not be a suitable alternative for many patients currently receiving dupilumab and PBS data indicating that upadacitinib accounted for only 15% of the total market.
- 5.11 The PBAC noted that the sponsor was yet to progress the March 2022 recommendation to expand the listing of dupilumab for severe atopic dermatitis to paediatric patients under 12 years. The PBAC strongly urged the sponsor to work with the Department to implement this recommendation as a priority.

Outcome:

Advice provided

6 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.

7 Sponsor's Comment

The sponsor had no comment.