7.02 NEMOLIZUMAB, Powder for injection containing nemolizumab 30 mg with diluent in pre-filled dual-chamber pen, Nemluvio®, Galderma Australia Pty Ltd

1 Purpose of submission

1.1 This Standard re-entry submission requested a General Schedule Authority Required (Telephone/Online) listing of nemolizumab (NEMO) for the treatment of patients with severe atopic dermatitis (AD) affecting the whole body, face, and/or hands.

1.2 Listing was requested on the basis of a cost minimisation approach (CMA) versus dupilumab (DUPI).

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

Component	Description
Population	Patients aged 12 years or older with chronic severe AD affecting the whole body or the face and/or hands, who are inadequately controlled on topical therapies.
Intervention	Initial treatment: Nemolizumab (NEMO) 60 mg SC injection as a loading dose, followed by 30 mg SC given Q4W for 16 weeks. Extended induction for slow responders at Week 16: NEMO 30 mg SC Q4W for a further 8 weeks[1] Continuing treatment: NEMO 30 mg SC Q8W
Comparator	In adult patients and in adolescents ≥ 60 kg: Dupilumab (DUPI) 600 mg SC injection as a loading dose, followed by 300 mg SC injection Q2W In adolescents 30 kg to < 60 kg: DUPI 400 mg SC injection as a loading dose, followed by 200 mg SC injection Q2W
Outcomes	Primary outcomes: Proportion of patients with a 75% improvement in EASI score (EASI-75) at Week 16; proportion of patients achieving IGA score of 0 or 1 with a ≥ 2-point improvement at Week 16. Secondary outcomes: Proportion of patients achieving a 50% improvement in EASI score (EASI-50); proportion of patients achieving a ≥ 4-point improvement in DLQI at Week 16; PP-NRS at Week 16. *Post-hoc* outcomes: Composite measure of response EASI-50 and improvement in DLQI ≥4-points at Week 16. EASI 75 at Week 24 (ITT), IGA score of 0 or 1 at Week 24 (ITT), EASI 50 at Week 24 (PBS [severe] population) Safety outcomes: Proportion of patients experiencing AEs, SAEs and discontinuation of treatment due to AEs.
Clinical claim	For the treatment of patients aged 12 years or older with chronic severe AD affecting the whole body or the face and/or hands, who are inadequately controlled on topical therapies, NEMO is non-inferior to DUPI in terms of efficacy and safety, based on their recommended dosing schedules.# In addition, NEMO offers the benefits of fewer injections and reduced rate of conjunctivitis, compared to DUPI.

Source: Table 1-1, p20 of the resubmission.
[1] Aligned with the proposed changes to the TGA label for NEMO, as detailed in Section 2 – Requested listing.
Abbreviations: AD = atopic dermatitis; AEs = adverse events; DLQI = Dermatology Life Quality Index; DUPI = dupilumab; EASI = Eczema Area Severity Index; NEMO = nemolizumab; PGA/ IGA = Physician's / Investigator's Global Assessment; PP-NRS = peak pruritus numerical rating scale; Q2W = every two weeks; Q4W = every four weeks; SC = subcutaneous; PBS = Pharmaceutical Benefits Scheme; SAEs = serious adverse events; TCS = topical corticosteroids.
Blue shading indicates information previously seen by the PBAC.

2 Background

Registration status

2.1 TGA approval was granted on 19 May 2025 for NEMO for the treatment of moderate-to-severe AD in combination with topical corticosteroids and/or topical calcineurin inhibitors in adults and in patients aged 12 years and above who weigh at least 30 kg, who are candidates for systemic therapy. Registration was finalised on 27 May 2025. The TGA indication is broader than the requested PBS listing in terms of disease severity.

2.2 On 23 February 2026, the TGA Delegate's Overview supported the inclusion of the following statement in Section 4.2, Dose and Method of Administration of the Product Information (PI) for AD: "Some patients with initial partial response may further improve with continued treatment beyond 16 weeks. Once clinical response is achieved, the recommended maintenance dose of nemolizumab is 30 mg every 8

weeks". The purpose of this addition is to allow for the extended induction period proposed in the resubmission.

Previous PBAC consideration

2.3 This was the second submission made for NEMO for the treatment of patients with severe AD affecting the whole body, face, and/or hands. NEMO was not recommended at the July 2025 PBAC meeting. The primary reason for this outcome was due to the comparative clinical evidence. The PBAC considered the July 2025 submission's clinical claim of non-inferior effectiveness of NEMO to DUPI was not adequately supported with the primary indirect comparison presented at 16 weeks indicating NEMO is likely inferior to DUPI. The Committee noted the additional clinical data presented in the Pre-Sub-Committee Response (PSCR) on improved patient outcomes with an extended induction period out to 24 weeks but noted this dosing regimen was not consistent with the TGA Product Information (PI), and as such could not be considered as part of the PBS listing (paragraphs 7.1 and 7.2, nemolizumab public summary document [PSD], July 2025 PBAC meeting). Table 2 details the key matters of concern from the previous submission.

Table 2: Summary of key matters of concern

Component	Matter of concern (July 2025 PSD)	How the resubmission addresses it
Clinical effectiveness	The indirect treatment comparisons (ITCs) were based on the intention-to-treat (ITT) populations from select NEMO and DUPI trials. These included patients with moderate to severe AD, which was broader than the proposed PBS population which is limited to patients with severe AD. In patients with moderate or severe AD, NEMO had inferior efficacy in comparison to DUPI at Week 16 in terms of (i) eczema area and severity index (EASI)-75 (RR = 0.61; 95% CI: 0.41, 0.90); and (ii) investigators global assessment (IGA) success (RR: 0.48; 95% CI: 0.34, 0.69) (para 7.5).	The resubmission presented updated comparative data for the PBS aligned subgroup of the trials but only for the EASI-50 outcome. These data included patients who underwent an extended induction period with NEMO if they did not have an adequate response at Week 16.
Safety	The ITCs presented for safety outcomes (any treatment-emergent adverse events (TEAEs), serious TEAEs, and TEAEs leading to discontinuation) may not allow for a meaningful comparison of NEMO and DUPI. In addition, the ITCs of serious TEAEs and TEAEs leading to discontinuation were statistically underpowered (para 7.7).	No additional comparative safety data were presented.
Financial estimates	The PBAC considered the uptake rates applied to the financial estimates in the submission were uncertain and likely overestimated, given the evidence suggests that NEMO is inferior compared to DUPI in terms of effectiveness. Overall, the PBAC considered the estimated savings to the PBS/RPBS associated with the listing of NEMO are likely overestimated and unlikely to be realised.	The resubmission reduced the uptake rate by [redacted]%, but there was no basis provided for the reduction.

Source: Compiled during the evaluation.
AD = atopic dermatitis; CMA = cost-minimisation approach; DUPI = dupilumab; ITC = indirect treatment comparison; NEMO = nemolizumab; PBAC = pharmaceutical benefits advisory committee; PBS/RPBS = pharmaceutical benefits scheme/ repatriation pharmaceutical benefits scheme; PSD = public summary document; TEAE = treatment emergent adverse event.

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

3 Requested listing

3.1 The proposed restrictions are presented below. Secretariat suggested addition are in italics and deletions in strikethrough.

Name, restriction, manner of administration, form	Max. qty packs	Max qty units	No. of Rpts	DPMQ	Proprietary name and manufacturer
Initial treatment					
NEMOLIZUMAB 30 mg/0.49 ml injection, 1 x 0.49 ml pen device	2	2	2	Effective: TBC Published: $5,418.35	Nemluvio Galderma Australia Pty Ltd
Extended induction treatment					
NEMOLIZUMAB 30 mg/0.49 ml injection, 1 x 0.49 ml pen device	2	2	0	Effective: TBC Published: $5,418.35	Nemluvio Galderma Australia Pty Ltd
Grandfather treatment					
NEMOLIZUMAB 30 mg/0.49 ml injection, 1 x 0.49 ml pen device	1	1	3	Effective: TBC Published: $2,790.64	Nemluvio Galderma Australia Pty Ltd
Continuing treatment					
NEMOLIZUMAB 30 mg/0.49 ml injection, 1 x 0.49 ml pen device	1	1	2	Effective: TBC Published: $2,790.64	Nemluvio Galderma Australia Pty Ltd

3.2 For brevity reasons, the following administrative advice notes that apply across all treatment phases of NEMO (whole body and face/eyelids), have not been reproduced in full in the restrictions:

	Administrative Advice: No increase in the maximum quantity or number of units may be authorised.
	Administrative Advice: No increase in the maximum number of repeats may be authorised.
	Administrative Advice: Special Pricing Arrangements apply.
	Administrative Advice: The Eczema Area and Severity Index (EASI) referenced in this restriction is that described in the following literature publications: Chalmers JR et al. Report from the third international consensus meeting to harmonise core outcome measures for atopic eczema/dermatitis clinical trials (HOME). *British Journal of Dermatology* 2014 December;171(6):1318-25. Schmitt J et al. HOME initiative collaborators. The Harmonising Outcome Measures for Eczema (HOME) statement to assess clinical signs of atopic eczema in trials. *The Journal of Allergy and Clinical Immunology* 2014 October;134(4):800-7
	Administrative Advice: Instructions on the use of the Dermatology Life Quality Index and copyright details can be found here: https://www.cardiff.ac.uk/medicine/resources/quality-of-life-questionnaires/dermatology-life-quality-index
	Administrative Advice: The Physician's Global Assessment (5-point scale) referenced in this restriction is that described in the following literature publication:

	Fatumura M et al. A systematic review of Investigator Global Assessment (IGA) in atopic dermatitis (AD) trials: Many options, no standards Journal of the American Academy of Dermatology 2016; 674(2): 288-94 The overall appearance of dermatitis lesions is rated as 4 (severe) if the lesions are best described as featuring: deep/dark red erythema, with marked and extensive induration/papulation; excoriation and oozing/crusting are present.
	Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Initial

MEDICINAL PRODUCT medicinal product pack	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
NEMOLIZUMAB					
nemolizumab 30 mg injection [1 chamber] (&) inert substance diluent [1 chamber], 1 dual chamber pen device	NEW	2	2	2	Nemluvio

Category / Program: ☒ GENERAL - General Schedule (Code GE)
Prescriber type: ☒ Medical Practitioners
Benefit type: ☒ Authority Required (Telephone/Online PBS Authorities System)
Restriction Summary [new1] / Treatment of Concept: [new1A]
Indication: Chronic severe atopic dermatitis
Treatment Phase: Initial treatment of the whole body
Clinical criteria:
Patient must have a Physicians Global Assessment (PGA) (5-point scale) baseline score of at least 4 as evidence of severe disease despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days
AND
Clinical criteria:
Patient must have an Eczema Area and Severity Index (EASI) baseline score of at least 20 despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days
AND
Clinical criteria:
Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days
AND
Clinical criteria:
The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands
AND
Clinical criteria:
Patient must not have experienced an inadequate response to this biological medicine in this PBS indication
AND
Clinical criteria:
The treatment must be the sole PBS-subsidised biological medicine for this PBS indication

Treatment criteria:
Must be treated by a dermatologist; or
Must be treated by a clinical immunologist
Population criteria:
Patient must be 12 years of age or older
Prescribing Instructions: State each of the qualifying (i) PGA, (ii) EASI and (iii) DLQI scores in the authority application. Acceptable scores can be: (a) current scores; or (b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication. The EASI and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records. Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled in the patient's medical records.
Prescribing Instructions: *At the time of assessment of response, i.e., within 16 weeks of initial treatment, if adequate response hasn't been achieved, the prescriber can apply for an extended induction treatment (up to further 8 weeks of therapy) where there has been a partial response and the prescriber considers that extended induction doses could result in achieving adequate response.*
Restriction Summary [new2] / Treatment of Concept: [new2A]
Indication: Chronic severe atopic dermatitis
Treatment Phase: Initial treatment of the face and/or hands
Clinical criteria:
The condition must have at least 2 of the following Eczema Area and Severity Index (EASI) symptom sub-scores for erythema, oedema/papulation, excoriation, lichenification rated as severe despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; or
The condition must have affected at least 30% of the face/hands surface area despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days
AND
Clinical criteria:
Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days
AND
Clinical criteria:
The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands
AND
Clinical criteria:
The treatment must be the sole PBS-subsidised biological medicine for this PBS indication
AND
Clinical criteria:
Patient must not have experienced an inadequate response to this biological medicine in this PBS indication
Treatment criteria:
Must be treated by a dermatologist; or
Must be treated by a clinical immunologist
Population criteria:

Patient must be 12 years of age or older
Prescribing Instructions: State each of the 4 Eczema Area and Severity Index (EASI) symptom sub-score ratings (0 = none, 1 = mild, 2 = moderate, 3 = severe) for: (i) erythema, (ii) oedema/papulation, (iii) excoriation, (iv) lichenification Acceptable scores can be: (a) current scores; or (b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication. State the percentage face/hand surface area affected by the condition (must be at least 30%) where EASI symptom sub-scores are not provided. This percentage surface area can also be stated in addition to the EASI symptom sub-scores. The EASI/percentage surface area and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records. Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled are in the patient's medical records.
Prescribing Instructions: *At the time of assessment of response, i.e., within 16 weeks of initial treatment, if adequate response hasn't been achieved, the prescriber can apply for an extended induction treatment (up to further 8 weeks of therapy) where there has been a partial response and the prescriber considers that extended induction doses could result in achieving adequate response.*

Extended induction restriction

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
NEMOLIZUMAB					
nemolizumab 30 mg injection [1 chamber] (&) inert substance diluent [1 chamber], 1 dual chamber pen device	NEW	2	2	0	Nemluvio

Category / Program: ☒ GENERAL - General Schedule (Code GE)
Prescriber type: ☒ Medical Practitioners
Benefit type: ☒ Authority Required (Telephone/Online PBS Authorities System)
Restriction Summary [new3] / Treatment of Concept: [new3A]
Indication: Chronic severe atopic dermatitis
Treatment Phase: Extended induction treatment (further 8 weeks of initial treatment of the whole body or the face and/or hands)
Clinical criteria:
Patient must have received PBS-subsidised treatment with this biological medicine for the treatment of chronic severe atopic dermatitis under the initial treatment or grandfather treatment phase of the whole body or the face and/or hands
AND
Clinical criteria:
Patient must not be undergoing each of: (i) commencing treatment through this treatment phase listing, (ii) treatment accessed through this treatment phase more than once;
AND
Clinical criteria:
Patient must not have achieved adequate response after 16 weeks of ~~initial~~ treatment with this drug ~~in~~ *for* this PBS indication;

AND
Clinical criteria:
The treatment must be the sole PBS-subsidised biological medicine for this PBS indication
Treatment criteria:
Must be treated by a dermatologist; or
Must be treated by a clinical immunologist
~~**AND**~~
Population criteria:
Patient must be 12 years of age or older
Prescribing Instructions: For the purposes of this restriction, an adequate response to treatment of the face/hands is defined as: (a) (i) A rating of either mild (1) to none (0) on at least 3 of the assessments of erythema, oedema/papulation, excoriation and lichenification mentioned in the Eczema Area and Severity Index (EASI); or (ii) At least a 75% reduction in the skin area affected by this condition compared to baseline; and (b) An improvement in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline Document each qualifying response measure in the patient's medical records for PBS compliance auditing purposes
Prescribing Instructions: For the purposes of this restriction, an adequate response to treatment of whole body is defined as: (a) An improvement/maintenance in the Eczema Area and Severity Index (EASI) score of at least 50% compared to baseline; and (b) An improvement/maintenance in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline State each of the current EASI and DLQI scores for this authority application.
Prescribing Instructions: Prescriber must only apply for this treatment phase if the patient has had a partial response to treatment and the prescriber considers that further induction treatment (further 8 weeks of therapy) with this drug is likely to result in an adequate response.
Prescribing Instructions: A second assessment of response must be conducted between 24 to 28 weeks from the first administered dose of this drug to determine the patient's eligibility for continuing treatment. Where an assessment is not undertaken, the patient will not be eligible for ongoing treatment.

Continuing

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
NEMOLIZUMAB					
nemolizumab 30 mg injection [1 chamber] (&) inert substance diluent [1 chamber], 1 dual chamber pen device	NEW	1	1	2	Nemluvio

Category / Program: ☒ GENERAL - General Schedule (Code GE)
Prescriber type: ☒ Medical Practitioners
Benefit type: ☒ Authority Required (Telephone/Online PBS Authorities System)
Restriction Summary [new4] / Treatment of Concept: [new4A]
Indication: Chronic severe atopic dermatitis
Treatment Phase: Continuing or resuming treatment of the whole body
Clinical criteria:
Patient must have received PBS-subsidised treatment with this biological medicine for the treatment of chronic severe atopic dermatitis affecting the whole body

AND
Clinical criteria:
Patient must have achieved an adequate response *prior to this first continuing treatment authority application;* ~~within the first 24 weeks of treatment;~~ or
Patient must have maintained an adequate response to their most recent course of PBS-subsidised treatment with this biological medicine for this PBS indication if this is the second or subsequent Continuing treatment authority application; or
Patient must have temporarily ceased treatment for reasons other than lack of response (e.g. family planning, vaccination with live vaccines, adverse-effect investigation), thereby being unable to achieve/maintain an adequate response immediately prior to this authority application
AND
Clinical criteria:
The treatment must be the sole PBS-subsidised biological medicine for this PBS indication
Treatment criteria:
Must be treated by a dermatologist; or
Must be treated by a clinical immunologist
Prescribing Instructions: For the purposes of this restriction, an adequate response to treatment of the whole body is defined as: (a) An improvement/maintenance in the Eczema Area and Severity Index (EASI) score of at least 50% compared to baseline; and (b) An improvement/maintenance in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline Where an initial baseline (post-topical corticosteroid, pre-biological medicine) DLQI score was not measured for a patient who had commenced treatment through a clinical trial, early access program or through private, non-PBS-subsidised supply, an absence of worsening in the current DLQI score compared to that measured at the time of the 'Grandfather listing' authority application will suffice as an adequate response for requirement (b) above. State each of the current EASI and DLQI scores for this authority application.
Restriction Summary [new5] / Treatment of Concept: [new5A]
Indication: Chronic severe atopic dermatitis
Treatment Phase: Continuing or resuming treatment of the face and/or hands
Clinical criteria:
Patient must have received PBS-subsidised treatment with this biological medicine for the treatment of chronic severe atopic dermatitis affecting the face/hands
AND
Clinical criteria:
Patient must have achieved an adequate response *prior to this first continuing treatment authority application;* ~~within the first 24 weeks of treatment~~; or
Patient must have maintained an adequate response to their most recent course of PBS-subsidised treatment with this biological medicine for this PBS indication if this is the second or subsequent Continuing treatment authority application; or
Patient must have temporarily ceased treatment for reasons other than lack of response (e.g. family planning, vaccination with live vaccines, adverse-effect investigation), thereby being unable to achieve/maintain an adequate response immediately prior to this authority application
AND
Clinical criteria:
The treatment must be the sole PBS-subsidised biological medicine for this PBS indication

~~**AND**~~
Treatment criteria:
Must be treated by a dermatologist; or
Must be treated by a clinical immunologist
Prescribing Instructions: For the purposes of this restriction, an adequate response to treatment of the face/hands is defined as: (a) (i) A rating of either mild (1) to none (0) on at least 3 of the assessments of erythema, oedema/papulation, excoriation and lichenification mentioned in the Eczema Area and Severity Index (EASI); or (ii) At least a 75% reduction in the skin area affected by this condition compared to baseline; and (b) An improvement in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline. Where an initial baseline (post-topical corticosteroid, pre-biological medicine) DLQI score was not measured for a patient who had commenced treatment through a clinical trial, early access program or through private, non-PBS-subsidised supply, an absence of worsening in the current DLQI score compared to that measured at the time of the 'Grandfather listing' authority application will suffice as an adequate response for requirement (b) above. State the current EASI ratings or the percentage of face/hand surface area affected by the condition. Also state the current DLQI score for this authority application.

Grandfather treatment

MEDICINAL PRODUCT **medicinal product pack**	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
NEMOLIZUMAB					
nemolizumab 30 mg injection [1 chamber] (&) inert substance diluent [1 chamber], 1 dual chamber pen device	NEW	1	1	3	Nemluvio

Category / Program: ☒ GENERAL - General Schedule (Code GE)
Prescriber type: ☒ Medical Practitioners
Benefit type: ☒ Authority Required (Telephone/Online PBS Authorities System)
Restriction Summary [new6] / Treatment of Concept: [new6A]
Indication: Chronic severe atopic dermatitis
Treatment Phase: Transitioning from non-PBS to PBS-subsidised *treatment* – 'Grandfather' arrangements *(whole body)* ~~supply – (treatment of the whole body)~~
Clinical criteria:
Patient must have been receiving non-PBS-subsidised treatment with this drug for this condition prior to [date of listing]
AND
Clinical criteria:
Patient must have had an Eczema Area and Severity Index (EASI) baseline score of at least 20 despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days prior to commencing non-PBS-subsidised therapy with this biological medicine
AND
Clinical criteria:
Patient must have had a Physicians Global Assessment (PGA) baseline score of at least 4 as evidence of severe disease despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days prior to commencing non-PBS-subsidised therapy with this biological medicine
AND
Clinical criteria:

Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, prior to having commenced non-PBS-subsidised therapy with this biological medicine; or
Patient must have, where the above baseline DLQI was not recorded in the patient's medical records, a current age-appropriate DLQI score (of any value) measured
AND
Clinical criteria:
The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands, prior to commencing non-PBS-subsidised therapy with this biological medicine
AND
Clinical criteria:
Patient must ~~not be experiencing~~ *have achieved* an ~~in~~adequate response to current non-PBS-subsidised therapy with this biological medicine, if they have received at least ~~24 weeks of therapy~~ *16 weeks of therapy (or 24 weeks of therapy in the case of slow responders).*
AND
Clinical criteria:
The treatment must be the sole PBS-subsidised biological medicine for this PBS indication
Treatment criteria:
Must be treated by a dermatologist; or
Must be treated by a clinical immunologist
Population criteria:
Patient must be 12 years of age or older
Prescribing Instructions: State each of the qualifying PGA, EASI and DLQI scores in the authority application. The name/s of the medium to high potency topical corticosteroids trialled prior to commencing treatment with this biological medicine must be documented in the patient's medical records. The EASI and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records.
Prescribing Instructions: A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under ~~the Continuing treatment criteria~~ one of the following: *(i) Continuing treatment, where there has been an adequate response to treatment* *(ii) Extended induction treatment (up to a further 8 weeks of therapy), where the patient has received 16 weeks of therapy, achieved a partial response and the prescriber considers that extended induction doses could result in achieving adequate response.*
Prescribing Instructions: This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.
Restriction Summary [new7] / Treatment of Concept: [new7A]
Indication: Chronic severe atopic dermatitis
Treatment Phase: Transitioning from non-PBS to PBS-subsidised *treatment* – 'Grandfather' arrangements *(face and/or hands)* ~~supply – (treatment of the face and/or hands)~~
Clinical criteria:
Patient must have been receiving non-PBS-subsidised treatment with this drug for this condition prior to [date of listing]
AND
Clinical criteria:

The condition must have had at least 2 of the following Eczema Area and Severity Index (EASI) symptom sub-scores for erythema, oedema/papulation, excoriation, lichenification rated as severe despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, prior to commencing non-PBS-subsidised therapy with this biological medicine; or
The condition must have affected at least 30% of the face/hands surface area despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, prior to commencing non-PBS-subsidised therapy with this biological medicine
AND
Clinical criteria:
Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, prior to commencing non-PBS-subsidised therapy with this biological medicine; or
Patient must have, where the above baseline DLQI was not recorded in the patient's medical records, a current age-appropriate DLQI score (of any value) measured
AND
Clinical criteria:
The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands, prior to commencing non-PBS-subsidised therapy with this biological medicine
AND
Clinical criteria:
The treatment must be the sole PBS-subsidised biological medicine for this PBS indication
AND
Clinical criteria:
Patient must ~~not be experiencing~~ *have achieved* an ~~in~~adequate response to current non-PBS-subsidised therapy with this biological medicine, if they have received at least ~~24 weeks of therapy~~ *16 weeks of therapy (or 24 weeks of therapy in the case of slow responder).*
Treatment criteria:
Must be treated by a dermatologist; or
Must be treated by a clinical immunologist
Population criteria:
Patient must be at least 12 years of age.
Prescribing Instructions: State each of the 4 Eczema Area and Severity Index (EASI) symptom sub-score ratings for erythema, oedema/papulation, excoriation, lichenification that were present prior to having commenced non-PBS-subsidised therapy, in the authority application. The name/s of the medium to high potency topical corticosteroids trialled prior to commencing treatment with this biological medicine is/are to be documented in the patient's medical records. Alternatively, state the percentage of face/hand surface area affected by the condition (must be at least 30%) where EASI symptom sub-scores are not provided. This percentage surface area can also be stated in addition to the EASI symptom sub-scores. The EASI/percentage surface area and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records.

Prescribing Instructions: A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under ~~the Continuing treatment criteria.~~one of the following: *(i) Continuing treatment, where there has been an adequate response to treatment* *(ii) Extended induction treatment (up to a further 8 weeks of therapy), where the patient has received 16 weeks of therapy, achieved a partial response and the prescriber considers that extended induction doses could result in achieving adequate response.*
Prescribing Instructions: This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

3.3 A Special Pricing Arrangement (SPA) was requested for NEMO, as for DUPI and upadacitinib (UPA) for severe AD. The resubmission noted that the effective approved ex-manufacturer price (AEMP) of DUPI remains confidential and thus, the sponsor was unable to nominate an effective ex-manufacture price (EMP) for NEMO based on the CMA.

3.4 The published dispensed price for maximum quantity (DPMQ) for initial treatment in the previous submission was $5,504.50 and in the resubmission was $5,418.35. The published DPMQ for continuing and grandfathered treatment was $2,833.55 in the previous submission and was $2,790.64 in the resubmission. The difference in the proposed published NEMO price between the two submissions reflects the updated CMA taking into account the extended induction period for slow responders to NEMO therapy (see the "Economic analysis" section below). The published DPMQ for the extended induction period is the same as for the initial treatment ($5,418.35).

3.5 The requested PBS restrictions for the initial, continuing, and grandfathered phases of treatment with NEMO are similar to those presented in the previous submission. A notable difference is the inclusion of the requirement that patients must have achieved an adequate response within the first 24 weeks of treatment in the continuation restriction and that patients must not be experiencing an inadequate response to current non-PBS-subsidised therapy with this biological medicine, if they have received at least 24 weeks of therapy in the grandfathering restriction. These changes were made to align with the inclusion of an extended induction phase restriction.

3.6 The listing requests that if patients have not achieved adequate response (defined as an improvement/maintenance in EASI score of at least 50% compared to baseline and an improvement/maintenance in DLQI score of at least 4 points compared to baseline) at Week 16 of induction treatment (NEMO every 4 weeks [Q4W]), they may receive an additional 8 weeks of induction treatment. The inclusion of an extended induction phase aligns with the listing for lebrikizumab (LEB) that was approved at the March 2024 PBAC meeting (lebrikizumab is not currently listed on the PBS).

3.7 The extended induction phase listing includes the criterion that the "prescriber must only apply for this treatment phase if the patient has had a partial response to treatment and the prescriber considers that further induction treatment (further 8

weeks of therapy) with this drug is likely to result in an adequate response". It is not detailed what a partial response is or how the prescriber is to determine if further induction treatment is likely to result in an adequate response.

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

4 Population and disease

4.1 AD is the most common chronic inflammatory skin disease that affects 15% to 20% of children and up to 10% of adults[1]. Approximately 60% of patients develop AD in the first year of life and 90% within the first 5 years of life[2]. The condition is associated with other atopic manifestations such as asthma, allergic rhinitis, or food allergy[3]. AD is presented as areas of rashes and dryness with intense pruritus that commonly involve the creases of the elbows, behind the knees, across the ankles and may also involve the face, ears, and neck. The condition is often relapsing and affected patients are predisposed to bacterial and viral skin infections. AD involving the eyelid can cause blepharitis (general inflammation and redness of the eyelid) and conjunctivitis. AD impacts an individual's overall quality of life (QoL), as well as social, academic, and occupational performance, and 33% to 90% of affected adults have AD associated sleep disturbance[4,5].

4.2 AD is caused by a complex interaction between genetics, skin barrier dysfunction, immune dysregulation, and extrinsic factors resulting in cutaneous inflammation and related symptoms. The Janus kinase (JAK)-signal transducer and activator of transcription pathway results in the release of cytokines including interleukin (IL)-4, IL-13 and IL-31 that are responsible for the pathogenesis of AD and the cardinal symptoms of AD, such as pruritus[6].

4.3 Based on the current Australian and international management guidelines for AD[7,8], a stepwise treatment approach is applied. The baseline management includes optimal skin care with emollients/moisturisers, appropriate bathing practice, adjuvant therapies, and targeted treatment for acute flares. Patients with severe AD who

[1]Allergy & Anaphylaxis Australia. Eczema (atopic dermatitis). URL: https://allergyfacts.org.au /__interest/eczema/

[2] Eichenfield LF et al. Guidelines of care for the management of atopic dermatitis: section 1. Diagnosis and assessment of atopic dermatitis. *Journal of the American Academy of Dermatology*. 2014; 70(2): 338-351.

[3] Berke R, Singh A & Guralnick M. Atopic dermatitis: a overview. *American Family Physician*. 2012; 86(1): 35-42.

[4] Drucker AM et al. The Burden of Atopic Dermatitis: Summary of a Report for the National Eczema Association. *Journal of Investigative Dermatology*. 2017; 137(1): 26-30.

[5] Bawany F et al. Sleep Disturbances and Atopic Dermatitis: Relationships, Methods for Assessment, and Therapies. *The Journal of Allergy and Clinical Immunology*: In Practice. 2021; 9(4): 1488-1500.

[6] Dubin C, Del Duca E & Guttman-Yassky E. The IL-4, IL-13 and IL-31 pathways in atopic dermatitis. *Expert Review of Clinical Immunology*. 2021; 17(8): 835-852.

[7] Smith S et al. Atopic dermatitis in adults: An Australian management consensus. *Australasian Journal of Dermatology*. 2020; 61(1): 23-32.

[8] Wollenberg A et al. European guideline (EuroGuiDerm) on atopic eczema: part I - systemic therapy. *Journal of the European Academy of Dermatology and Venereology*. 2022; 36(9): 1409-1431.

cannot achieve adequate disease control[9] despite receiving a topical corticosteroid (TCS) or topical calcineurin inhibitor (TCI) for ≥ 28 days are eligible for systemic treatment with options such as immunosuppressants, monoclonal antibodies, or JAK inhibitors.

4.4 NEMO is a first in class humanised monoclonal antibody (IgG2) that inhibits interleukin-31 (IL-31). IL-31 is one of the key cytokines responsible for pruritus and inflammation in AD. In the NEMO Product Information (PI), it is stated that NEMO can be used with or without a TCS. TCIs may be used, but should be reserved for problem areas only, such as the face, neck, intertriginous and genital areas. Any use of topical therapies should be tapered and subsequently discontinued when the disease has sufficiently improved.

4.5 NEMO, if listed on the PBS, would provide an additional systemic treatment option for severe AD in patients who are inadequately controlled on topical therapies.

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

5 Comparator

5.1 DUPI was the nominated main comparator in the resubmission. This was consistent with the previous submission. DUPI is PBS listed for treating chronic severe AD involving the whole body, face, and/or hands.

5.2 The main arguments provided in the resubmission to support the nomination of DUPI as the main comparator include: 1) DUPI is the most utilised targeted therapy for treating severe AD in clinical practice (approximately 87% of PBS services) and hence, is the therapy most likely to be replaced by NEMO should NEMO be listed, and 2) in the submissions for other targeted therapies for severe AD (UPA, LEB, and abrocitinib [ABRO]) which utilised a CMA, DUPI was accepted as the main comparator .

5.3 In the context of the CMA taken by the submission, a further consideration for PBAC is that, under Section 101(3B) of the *National Health Act 1953*, when the proposed medicine is substantially more costly than an alternative therapy, the Committee cannot make a positive recommendation unless it is satisfied that, for some patients, the proposed medicine provides a significant improvement in efficacy and/or reduction of toxicity over the alternative therapy. If the Committee is so satisfied, it must make a statement to this effect.

5.4 For the requested population, the following PBS-listed medicines may be considered alternative therapies because they could be replaced in practice: DUPI and UPA.

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

[9] Refers to a state in which symptoms are absent or mild without daily activities being disturbed by AD (Smith et al. 2020)

6 Consideration of the evidence

Sponsor hearing

6.1 There was no sponsor hearing for this item; however, a written statement from a clinician who discussed the role of NEMO in the current Australian treatment landscape was provided. The clinician described the adverse events associated with dupilumab, currently the most commonly used biological medication for the treatment of severe atopic dermatitis. These include conjunctivitis (incidence of up to 62%)[10], ocular surface disorders, "red face" syndrome, injection site reactions and the development of arthritis, and they lead to discontinuation of dupilumab in approximately 5% of patients. The clinician stated that NEMO has a favourable safety profile, with rates of conjunctivitis and placebo no higher than with placebo, is not associated with "red face" or arthritis and has a low rate of injection site reactions.

6.2 The clinician also highlighted that NEMO has a novel mechanism of action and as multiple mechanisms lead to similar skin manifestations, there is a high need for additional treatment options.

Consumer input

6.3 The PBAC noted and welcomed the input from individuals (1) and organisations (3) via the Office of Health Technology Assessment Consultation Hub. The individual had received NEMO via a clinical trial for their AD and stated that their skin cleared completely, they had a reduction in environmental allergy reactivity, reduced frequency of cold sores and stabilisation of lipoedema. The individual reported no adverse events while on treatment and stated that their quality of life improved significantly.

6.4 The PBAC noted input from the Australian College of Dermatologists, the Australian Society of Clinical Immunology and Allergy and a joint submission from Allergy & Anaphylaxis Australia and the National Allergy Council. The PBAC recalled that these organisations, which had also provided input in July 2025, described the impacts of severe AD on an individuals' ability to participate in social, work and educational activities and the severe itch, which affects sleep and can increase the risk of infection, all of which impact quality of life. The inputs noted that the addition of NEMO to the PBS would provide an alternate treatment options for patients.

Clinical studies

6.5 The trials included in the resubmission were the same as in the previous submission. The primary difference is the use of data from the ARCADIA longer term extension

[10] Kamata M, Tada Y. A Literature Review of Real-World Effectiveness and Safety of Dupilumab for Atopic Dermatitis. *JID Innov*. 2021;1(3):100042. Published 2021 Jul 30. doi:10.1016/j.xjidi.2021.100042

(LTE) study out to 104 weeks and the use of an extended induction period for patients in the ARCADIA LTE to inform a naïve indirect treatment comparison (ITC).

6.6 Details of the studies presented in the resubmission are provided in Table 3.

Table 3: Trials/studies and associated reports presented in the resubmission

Trial ID	Protocol title/ Publication title	Publication citation
Nemolizumab		
ARCADIA 1 NCT03985943 **ARCADIA 2** NCT03989349	ARCADIA 1 CSR (NCT03985943) Efficacy and safety of nemolizumab in subjects with moderate-to-severe atopic dermatitis	18 September 2023
	ARCADIA 2 CSR (NCT03989349) Efficacy & safety of nemolizumab in subjects with moderate-to-severe atopic dermatitis	19 September 2023
	Silverberg, J. I., Wollenberg, A., et al. Nemolizumab with concomitant topical therapy in adolescents and adults with moderate-to-severe atopic dermatitis (ARCADIA 1 and ARCADIA 2): results from two replicate, double-blind, randomised controlled phase 3 trials.	The Lancet 2024; 404(10451) 445-460
ARCADIA CYCLO NCT05056779 EUCTR2021-002166-40	ARCADIA CYCLO CSR Efficacy and safety of nemolizumab in subjects with moderate-to-severe atopic dermatitis with inadequate response to or for whom cyclosporine A is not medically advisable	21 February 2024
ARCADIA LTE	ARCADIA LTE CSR A Prospective, Multicentre, Long-Term Study to Assess the Safety and Efficacy of Nemolizumab (CD14152) in Subjects with Moderate-to-Severe Atopic Dermatitis	10 October 2023
	Augustin, M., Tauber, M., et al. Safety and efficacy of nemolizumab for atopic dermatitis up to 2 years in open-label extension study	Journal of the European Academy of Dermatology and Venereology 2025; Epub ahead of print.
Study 114322 NCT03100344 EUCTR2016-005025-37	Study 114322 CSR Dose-ranging study of nemolizumab in atopic dermatitis	29 May 2019
	Silverberg, J. I., Pinter, A., et al. Phase 2B randomized study of nemolizumab in adults with moderate-to-severe atopic dermatitis and severe pruritus	Journal of Allergy & Clinical Immunology 2020; 145(1)173-182
Dupilumab		
LIBERTY AD CAFÉ NCT02755649	A study to assess the efficacy and safety of dupilumab in participants with severe atopic dermatitis (AD) that are not controlled with oral cyclosporine A (CSA) or for those who cannot take oral CSA because it is not medically advisable. https://clinicaltrials.gov/study/NCT02755649	August 2020
	de Bruin-Weller, M., Thaci, D., et al. Dupilumab with concomitant topical corticosteroid treatment in adults with atopic dermatitis with an inadequate response or intolerance to ciclosporin A or when this treatment is medically inadvisable: a placebo-controlled, randomized phase III clinical trial (LIBERTY AD CAFÉ)	British Journal of Dermatology 2018; 178(5) 1083-1101
LIBERTY AD CHRONOS NCT02260986	Study to assess the efficacy and long-term safety of dupilumab (REGN668/SAR231893) in adult participants with moderate-to-severe atopic dermatitis (CHRONOS). https://clinicaltrials.gov/study/NCT02260986	October 2017
	Blauvelt, A., de Bruin-Weller, M., et al. Long-term management of moderate-to-severe atopic dermatitis with dupilumab and concomitant topical corticosteroids (LIBERTY AD CHRONOS): a 1-year, randomised, double-blinded, placebo-controlled, phase 3 trial	The Lancet 2017; 389(10086) 2287-2303

Trial ID	Protocol title/ Publication title	Publication citation
JADE COMPARE NCT03720470	Study evaluating efficacy and safety of PF-04965842 and dupilumab in adult subjects with moderate to severe atopic dermatitis on background topical therapy (JADE Compare). https://clinicaltrials.gov/study/NCT03720470	January 2021
	Bieber, T., Simpson, E. L., et al. Abrocitinib versus placebo or dupilumab for atopic dermatitis	New England Journal of Medicine 2021; 384(12) 1101-1112

Source: Table 2-5, p46 of the resubmission.
CSR = clinical study report.
Notes: Including key study publications only.
Blue shading indicates studies previously seen by the PBAC

6.7 The key features of the included evidence are summarised in Table 4.

Table 4: Key features of the included evidence

Trial	N	Design/ duration	Risk of bias	Patient population	Outcomes	Used in CMA?
Nemolizumab vs. placebo						
ARCADIA 1	941	R, DB, MC 48 weeks	Low	Adult and adolescent patients with moderate to severe AD with inadequate response to topical steroids	EASI-75 IGA success EASI-50 ≥4-point improvement in DLQI ≥4-point improvement in PP-NRS Safety	Yes
ARCADIA 2	787	R, DB, MC 48 weeks	Low	Adult and adolescent patients with moderate to severe AD with inadequate response to topical steroids	EASI-75 IGA success EASI-50 ≥4-point improvement in DLQI ≥4-point improvement in PP-NRS Safety	Yes
ARCADIA CYCLO	276	R, DB, MC 16 weeks	Low	Adult patients with moderate to severe AD with recent exposure to CsA or medically inadvisable to received CsA	EASI-75 IGA success EASI-50 Safety	-
Study 114322	114	R, DB, MC 24 weeks	Low	Adult patients with moderate to severe AD with inadequate response to topical steroids	EASI-75 IGA success EASI-50 ≥4-point improvement in DLQI Safety	-
Meta-analysis	2,118	Included ARCADIA 1, ARCADIA 2, and Study 114322 for efficacy and ARCADIA 1, ARCADIA 2, ARCADIA CYCLO, and Study 114322 for safety.				-
ARCADIA LTE	1,901	OL, MC	High	Patients from previous NEMO trials (both responders and those who did not respond at week16) as well as NEMO naïve adolescent patients.	IGA EASI SCORAD DLQI Safety	Yes
Dupilumab vs placebo						

Trial	N	Design/ duration	Risk of bias	Patient population	Outcomes	Used in CMA?
CHRONOS	421	R, DB, MC 1 year	Low	Adult patients with moderate to severe AD with inadequate response to topical steroids	EASI-75 IGA success EASI-50 ≥4-point improvement in DLQI ≥4-point improvement in PP-NRS Safety	-
JADE COMPARE	373	R, DB, MC 24 weeks.	Low	Adult patients with moderate to severe AD with inadequate response to topical steroids	EASI-75 IGA success EASI-50 ≥4-point improvement in DLQI ≥4-point improvement in PP-NRS Safety	-
CAFÉ	215	R, DB, MC 16 weeks	Low	Adult patients with moderate to severe AD with inadequate response to topical steroids	EASI-75 IGA success EASI-50 ≥4-point improvement in DLQI ≥4-point improvement in PP-NRS Safety	-
Meta-analysis	1,009	Included CHRONOS, and JADE COMPARE for efficacy and CHRONOS, JADE COMPARE, and CAFÉ for safety.				-

Source: Compiled during the evaluation, based on Section 2.3.2, pp86-91 and Table 2-26, 146 of the resubmission.
AD = atopic dermatitis; CsA = cyclosporine A; DB = double blind; DLQI = Dermatology Life Quality Index; EASI-50/75 = improvement of at least 50%/75% from baseline in Eczema Area and Severity Index; IGA = Investigator's Global Assessment; MC = multi-centre; OL = open label; PP-NRS = Peak Pruritus Numerical Rating Score; R = randomised.
Note: some trials had multiple intervention treatment arms but only those that used the recommended dose regimens for NEMO and DUPI were presented in the resubmission.
Blue shading indicates data previously seen by the PBAC.

6.8 ARCADIA LTE enrolled adolescent patients (aged 12 to 17) who had not participated in previous NEMO studies, in addition to patients from seven phase 2 and phase 3 trials, including the ARCADIA trials. Individuals who had an adequate response to NEMO at 16 weeks as well as patients who did not have an adequate response at 16 weeks were included. All patients received 30 mg NEMO Q4W, which aligns with the dosing for the induction phase proposed in the PBS listing.

6.9 To inform the ITCs, the resubmission used data from patients who did not have an adequate response to NEMO at Week 16 and then went on to receive an additional 8 weeks of Q4W NEMO in the ARCADIA LTE study. As a consequence of its design, the data used to inform the ITC with DUPI was derived from *post-hoc* analyses, of non-blinded and non-randomised studies, resulting in a high risk of bias. The PSCR provided the characteristics of the non-responder sub-group, noting that there was no evidence of prognostic factors or effect modifiers that may have been driving the observed effect of NEMO or that the subgroups were biased. The ESC however noted that there were differences in the proportion of patients with an Investigator's Global Assessment (IGA) score of 4 (100% in ARCADIA LTE patients with a EASI-50 (i.e. the proposed PBS population) compared to approximately 30% in the ARCADIA trials) and body surface area (59.5% in ARCADIA LTE compared to approximately 44.0% in the ARCADIA trials).

6.10 The transitivity issues with the ITC from the previous submission remain in the updated ITCs. Briefly, the previous noted transitivity issues were:

- The two NEMO trials with the largest sample sizes, i.e. ARCADIA 1 and ARCADIA 2, enrolled patients aged ≥ 12 years; whereas all included DUPI trials and the other two NEMO trials included adult patients ≥ 18 years of age only.
- Of the trials included in the efficacy ITCs, ARCADIA 1, ARCADIA 2, CHRONOS and JADE COMPARE required patients to have an EASI score of ≥ 16 at baseline, compared to an EASI score of ≥ 12 in Study 114322.
- The proportion of patients having an IGA of 4 (corresponds to severe AD) at baseline was lower in NEMO trials than in DUPI trials (31% vs. 40%).

The direction and magnitude of the impact of the observed differences across trial sets on the ITC results could not be estimated.

Comparative effectiveness

6.11 Table 5 presents the results of the ITCs from the previous submission. Based on this evidence, in July 2025 the PBAC considered the submission's clinical claim of non-inferior effectiveness of NEMO versus DUPI was not adequately supported given the primary indirect comparison presented at 16 weeks indicated that NEMO is likely inferior to DUPI (paragraph 7.1, nemolizumab PSD, July 2025 PBAC meeting). The PBAC noted for the presented ITCs, the results were in favour of DUPI for the co-primary endpoints of Eczema Area and Severity Index (EASI)-75[11] (RR = 0.61; 95% CI: 0.41, 0.89) and IGA[12] success (RR = 0.49; 95% CI: 0.34, 0.69). Additionally, the PBAC noted the resubmission did not present ITCs of NEMO versus DUPI in the proposed target population of patients with severe AD. Instead, the resubmission provided *post-hoc* subgroup analyses for patients with severe AD from the NEMO trials only (paragraph 7.5, nemolizumab PSD, July 2025 PBAC meeting).

[11] The EASI score is a composite score ranging from 0–72. The severity of erythema (E), induration/papulation (I), excoriation (Ex), and lichenification (L) based on Investigator or trained designee on a scale of 0 (absent) to 3 (severe) for each of the four body areas: head/neck, trunk, upper limbs, and lower limbs, with half points allowed

[12] The IGA is a 5-point scale used by the Investigator or trained designee to evaluate the global severity of AD and the clinical response to treatment. The levels are:

- 0 (clear – minor, residual hypopigmentation/hyperpigmentation, no erythema or induration/papulation, no oozing/crusting),
- 1 (almost clear – trace faint pink erythema, with barely perceptible induration/papulation and no oozing/crusting),
- 2 (mild – faint pink erythema with mild induration/papulation and no oozing/crusting),
- 3 (moderate – pink-red erythema with moderate induration/papulation with or without oozing/crusting),
- 4 (severe – deep or bright red erythema with severe induration/papulation with oozing/crusting)

Table 5: Results of the ITCs of NEMO 30 mg Q4W (pooled excl. ARCADIA CYCLO) vs DUPI 300 mg Q2W (pooled excl. CAFÉ) presented in the previous submission – ITT population

Outcome	Relative risk (95% CI)	Risk difference (95% CI)
EASI-75 at week 16	**0.61 (0.41, 0.90)**	**-0.24 (-0.37, -0.12)**
IGA success at week 16	**0.49 (0.34, 0.69)**	**-0.14 (-0.22, -0.06)**
EASI-50 at week 16	0.72 (0.49, 1.05)	**-0.22 (-0.39, -0.05)**
≥4-point improvement in DLQI at Week 16	0.77 (0.57, 1.05)	**-0.17 (-0.32, -0.02)**

Source: Table 4, p14, Table 5 p14, Table 6, p16, and Table 7, p15 of the nemolizumab PSD, July 2025 PBAC meeting.
CI = confidence interval; DLQI = Dermatology Life Quality Index; DUPI = dupilumab; EASI-50 = proportion of patients with ≥ 50% improvement in Eczema Area and Severity Index from baseline; EASI-75 = proportion of patients with ≥ 75% improvement in Eczema Area and Severity Index from baseline; IGA = Investigator's Global Assessment; ITC = indirect treatment comparison; ITT = intention-to-treat; NEMO = nemolizumab; Q2W = every 2 weeks; Q4W = every 4 weeks.
Bold = statistically significant
Blue shading indicates data previously seen by the PBAC.

6.12 The resubmission presented data from ARCADIA LTE from the most recent data cut-off (DCO) of 21 July 2024 (follow-up data available to 104 weeks of treatment). The results were presented for IGA success, EASI-75, EASI-50, and ≥4-point improvement in Dermatology Life Quality Index (DLQI)[13] at the LTE baseline, Week 56 and Week 104. The enrolled patients were divided into those with previous NEMO exposure (PNE) and those with no NEMO exposure (NNE). The PNE group contains both patients who were adequate responders at Week 16 as well as those who did not have an adequate response.

Table 6: Key results from the ARCADIA LTE study (21 July 2024 DCO)

Outcome	Proportion of patients with response at LTE baseline (end of ARCADIA initial study)	Proportion of patients with response at Week 104	Difference in proportions from baseline to Week 104
IGA success (PNE)[1]	27.1%	62.6%	35.5%
IGA success (NNE)[2]	17.1%	58.2%	41.1%
EASI-75 (PNE)[1]	38.8%	88.2%	49.4%
EASI-75 (NNE)[2]	25.8%	85.4%	59.6%
EASI-50 (PNE)[1]	62.9%	96.3%	33.4%
EASI-50 (NNE)[2]	50.9%	97.3%	46.4%
≥4-point improvement in DLQI (PNE)[1]	76.3%	92.2%	15.9%
≥4-point improvement in DLQI (NNE)[2]	62.6%	91.0%	28.4%

Source: Figure 2-4, p54, Figure 2-5, p55, and Figure 2-6, p56 of the resubmission.
DCO = data cut-off); DLQI = Dermatology Life Quality Index; EASI-50 = proportion of patients with ≥ 50% improvement in Eczema Area and Severity Index from baseline; EASI-75 = proportion of patients with ≥ 75% improvement in Eczema Area and Severity Index from baseline; IGA = Investigator's Global Assessment; LTE = long term extension; NEMO = nemolizumab; PNE = previous NEMO exposure; NNE = no NEMO exposure.
[1] 1164 patients were enrolled who had previous nemolizumab exposure.
[2] 737 patients were enrolled who had no previous exposure to nemolizumab.
Italics = calculated during the evaluation.

6.13 The results presented in Table 6 show that, at Week 104 of NEMO treatment, more patients reported a positive response across all the key outcomes. These

[13] The DLQI is a 10-item questionnaire for patients aged > 16 years covering domains, including symptoms/feelings, daily activities, leisure, work/school, personal relationships, and treatment. The patient rated each question ranging from 0 (not at all) to 3 (very much). The DLQI total score was calculated by summing each questionnaire. The total score had a maximum score of 30 and a minimum of 0; a higher total score indicated a poorer QoL

improvements were seen across both the PNE group and the NNE group. Although the ARCADIA LTE study was unblinded and not comparative, these results suggest that extended treatment with NEMO may result in a greater proportion of patients reporting positive responses and that use of NEMO is associated with a sustained improvement in patient relevant outcomes, particularly for those who had not previously received NEMO. It should be noted that all patients received NEMO at Q4W for the duration of the ARCADIA LTE, rather than an induction period of Q4W followed by a maintenance period of NEMO every 8 weeks (Q8W), as detailed in the PI.

6.14 Table 7 presents the additional analyses from the ARCADIA LTE demonstrating the effects of an extended induction phase of an additional 8 and 20 weeks of NEMO Q4W in patients who did not achieve a full clinical response (EASI 75 or IGA 0/1) to the initial induction period of NEMO Q4W for 16 weeks. This data was provided in the PSCR to the previous submission. The resubmission stated that, based on these results, an additional 8 weeks of Q4W treatment with NEMO is expected to result in an additional 30.1% of intention-to-treat (ITT) patients demonstrating an EASI-75 response, an additional 9.6% of ITT patients demonstrating an IGA 0/1 response, and an additional 34.5% of patients in the severe AD PBS population demonstrating an EASI-50 response.

Table 7: Results of the LTE study: proportion of additional patients who respond with an additional 8 or 20 weeks of induction treatment with NEMO

Population	Outcome	LTE, N	LTE baseline response (16 weeks), n	N available to respond	Total responders at timepoint, n	Additional responders, n	% additional response from LTE[1]
Additional induction 8 weeks (24 weeks of induction therapy)							
ITT	EASI-75	937	356	581	531	175	30.1%
ITT	IGA 0/1	937	273	664	337	64	9.6%
PBS[2]	EASI-50	172	59	113	98	39	34.5%
Additional induction 20 weeks (36 weeks of induction therapy)							
ITT	EASI-75	937	356	581	569	213	36.7%
ITT	IGA 0/1	937	273	664	374	101	15.2%
PBS	EASI-50	172	59	113	114	55	48.7%
PBS	DLQI ≥ 4 point	172	105	67	114	9	13.4%
PBS	Composite	172	45	127	87	42	33.1%

Source: Table 2-10, p59 of the submission.
AD = atopic dermatitis; DLQI = Dermatology Life Quality Index; EASI = Eczema Area and Severity Index; IGA = Investigator's Global Assessment; ITT = intent to treat; LTE = long-term extension; NEMO = nemolizumab; PBS = Pharmaceutical Benefits Scheme; PGA = Physician's Global Assessment.
[1] Calculated as additional responders in LTE divided by those patients who entered LTE following treatment with NEMO in ARCADIA 1 or 2 as non-responders
[2] Subgroup population with severe AD only defined as an EASI score ≥ 20 and an PGA/IGA score of 4
Blue shading indicates data previously seen by the PBAC

6.15 Table 8 presents an analysis of the proportion of patients achieving relevant efficacy outcomes with an additional 8 weeks of NEMO Q4W (i.e., induction extended to 24 weeks). The outcomes are EASI-50 in the severe PBS population, as well as IGA 0/1 and EASI-75 in the ITT population. Of note, DLQI data was not collected at the 8-week

timepoint in the LTE (thereby prohibiting an analysis of both DLQI ≥4 improvement, and the composite endpoint of DLQI ≥4 improvement from baseline and EASI-50 in both the ITT and PBS populations).

Table 8: Naïve (unanchored and unadjusted) indirect comparison of NEMO 24 weeks (16 + 8) and DUPI 16 weeks response rates

		NEMO Week 16 from trial				Additional 8 weeks (i.e. up to 24 weeks initial period)			DUPI response at 16 weeks[a]
Pop	Outcome	n	N	% response	Non-responders in ARCADIA 1&2, n	% additional response from LTE[b]	Expected total responders after 24 weeks, n[d]	Total NEMO response at 24 weeks	
ITT	EASI-75	490	1,142	42.9%	652	30.1%	686	60.1%	64.2%
ITT	IGA 0/1	418	1,142	36.6%	724	9.6%	488	42.7%	38.2%
PBS[c]	EASI-50	164	330	49.7%	166[e]	34.5%	221	67.1%	67.0%

Source: Table 2-11, p59 of the resubmission. AD = atopic dermatitis; DUPI = dupilumab; EASI = Eczema Area and Severity Index; IGA = Investigator's Global Assessment; ITT = intent to treat; LTE = long-term extension; NEMO = nemolizumab; PBS = Pharmaceutical Benefits Scheme; PGA = Physician's Global Assessment.

[a] Derived from LEB PSD, March 2024 PBAC meeting

[b] Calculated as additional responders in LTE (displayed in Table 7) divided by those patients who entered LTE following treatment with NEMO in ARCADIA 1 or 2 as non-responders.

[c] Subgroup population with severe AD only defined as an EASI score ≥ 20 and an PGA/IGA score of 4

[d] The number of expected total responders was calculated by taking the observed additional response rate from Table 7 and applying it to the number of non-responders at week 16 in ARCADIA 1 and ARCADIA 2. This was then added to the number of responders at week 16 in ARCADIA 1 and ARCADIA 2.

[e] For the EASI-50 outcome measured in the PBS population, there were 166 patients who did not respond in ARCADIA 1 and ARCADIA 2. However, only 113 of these patients continued to ARCADIA LTE, leaving 53 patients who did not continue.

6.16 Although the results presented in Table 8 suggest that the response rate of NEMO with an extended induction phase is non-inferior to the response rate of DUPI at 16 weeks, the ESC noted that there are several issues with the analyses. The data from the ARCADIA LTE is single arm, open-label, and is a *post-hoc* selected subgroup consisting of patients who did not respond at Week 16. Because randomisation was lost after Week 16 and continuation into the extension phase was influenced by clinical judgement and patient behaviour, the extension outcomes are subject to selection bias and informative continuation that cannot be quantified or adjusted for. As a result, the ITC compares a randomly selected ITT population in the DUPI treatment arm with an uncharacterised, selectively enriched, and potentially biased subgroup from the ARCADIA LTE trial, meaning that the conclusions were uncertain.

6.17 In addition to the above issues, only the EASI-50 outcome is presented for the severe AD population that aligns with the requested PBS population. Although EASI-50 has been used to inform decision making in previous submissions, the PBAC has expressed a preference for the composite outcome of EASI-50 and ≥ 4-point improvement in DLQI.

6.18 To support the results of the extended induction phase, the resubmission presented a statistical analysis to account for non-responders who did not enter the ARCADIA LTE. The three scenarios presented were:

- Best case – all non-responding patients at 16 weeks who did not enter the extension study are assumed to be responders at 24 weeks.
- Average case – non-responding patients at 16 weeks who did not enter the extension study are assumed to respond at the same rate as non-responding patients at 16 weeks who did enter the extension study.
- Worst case – all non-responding patients at 16 weeks who did not enter the extension study are assumed to be non-responders at 24 weeks.

6.19 The results of the three scenarios and a comparison to the findings in the DUPI treatment arm are presented in Table 9.

Table 9: Meta-estimates of the percentage of responders in treatment arms

	Meta-estimates		Difference (NEMO – DUPI)
	NEMO, 24 weeks % (95% CI)	DUPI, 16 weeks % (95% CI)	
ITT population			
EASI-75, (NEMO best case)	64.5% (61.1%, 67.7%)	64.1% (59.6%, 68.4%)	0.40%
EASI-75, (NEMO average case)	60.2% (57.3%, 63.0%)	64.1% (59.6%, 68.4%)	–3.90%
EASI-75, (NEMO worst case)	58.2% (55.4%, 61.1%)	64.1% (59.6%, 68.4%)	–5.90%
IGA, (NEMO best case)	47.6% (42.1%, 53.3%)	38.3% (33.9%, 42.8%)	9.30%
IGA, (NEMO average case)	42.7% (39.9%, 45.6%)	38.3% (33.9%, 42.8%)	4.40%
IGA, (NEMO worst case)	42.2% (39.4%, 45.1%)	38.3% (33.9%, 42.8%)	3.90%
Severe population			
EASI-50, (NEMO best case)	77.5% (72.7%, 81.7%)	67.0% (61.5%, 72.1%)	10.50%
EASI-50, (NEMO average case)	67.2% (60.2%, 73.5%)	67.0% (61.5%, 72.1%)	0.20%
EASI-50, (NEMO worst case)	61.4% (54.6%, 67.8%)	67.0% (61.5%, 72.1%)	–5.60%

Source: Table 2-15, pp64-65 and Table 2-16, p65.
CI = confidence interval; DUPI = dupilumab; EASI = Eczema Area and Severity Index; IGA = Investigator's Global Assessment; ITT = intent to treat; NEMO = nemolizumab.

6.20 The PBS population had a better response rate under the best-case scenario, by EASI-50, with NEMO than with DUPI, while under the worst-case scenario they had a worse response rate, and with the average scenario, the response rate between NEMO and DUPI was similar. However, the non-responder patients who did not carry on to the ARCADIA LTE may have been judged as unlikely to respond or who could not carry on with treatment due to toxicity and hence, would not benefit from an extended induction period, the ESC considered that the most reasonable assumption is the "worst-case" scenario where none of these patients respond, or at least a scenario where many of these patients do not respond.

6.21 The evaluation noted that the approach, which included the analysis of long-term extension data and an updated economic analysis, aligned with that used in the LEB submission[14].

Comparative harms

6.22 The resubmission presented an overall summary of treatment emergent adverse events (TEAEs) at the 21 July DCO of the ARCADIA LTE, representing 104 weeks of treatment (Table 10).

6.23 The number of TEAEs experienced by patients in the ARCADIA LTE was higher than what was reported in ARCADIA 1 and ARCADIA 2, which is to be expected given the longer treatment duration. Difference in TEAEs in the PNE and NNE groups were not presented. The resubmission stated that there was no new safety findings observed, with the most common study drug-related TEAEs being AD, asthma, nasopharyngitis and upper respiratory tract infection.

6.24 Treatment-emergent adverse events of special interest (AESI) were mild-to-moderate and experienced by 29.2% of patients during the treatment period, most of which were infections (24.9%). Of note is that the proportion of TEAEs leading to treatment discontinuation was low (4.7%) indicating that long term use of NEMO is well tolerated and that drug related AEs were able to be resolved.

[14] lebrikizumab-psd-march-2024.pdf

Table 10: Summary of key adverse events in the ARCADIA LTE study

	Total study population (N=1901) n (%)	EAIR/100 person year	EAER/100 person year
AEs or SAEs			
Any TEAE	1510 (79.4)	114.4	205.4
Any TEAE related to study drug	421 (22.1)	12.7	26.9
Any serious TEAE	154 (8.1)	4.1	5.0
Any serious TEAE related to study drug	17 (0.9)	0.4	0.5
Any severe TEAE	140 (7.4)	3.7	5.1
Any TEAE leading to temporary discontinuation of study drug	261 (13.7)	7.3	9.5
Any TEAE leading to permanent discontinuation of study drug	90 (4.7)	2.3	2.7
Any TEAE leading to permanent discontinuation from study	88 (4.6)	2.2	2.6
Any TEAE leading to death	0	0	0
AESI			
Infections	473 (24.9)	15.1	15.0
Peripheral oedema: limbs, bilateral; facial oedema	34 (1.8)	0.9	1.3
Injection-related reactions	2 (0.1)	0.1	0.1
TEAEs with overall incidence ≥5% (MedDRA preferred term)			
COVID-19	372 (19.6)	11.3	11.4
Nasopharyngitis	370 (19.5)	10.9	19.8
Upper respiratory tract infection	241 (12.7)	6.7	9.7
Headache	123 (6.5)	3.3	5.4
Asthma	105 (5.5)	2.8	3.7
Dermatitis atopic	344 (18.1)	9.8	13.8

Source: Table 2-9, p57 of the resubmission.

AE = adverse event; AESI = adverse event of special interest; COVID-19 = coronavirus disease 2019; EAER = exposure-adjusted event rate; EAIR = exposure-adjusted incidence rate; MedDRA = Medical Dictionary for Regulatory Activities; N = total number of patients; n = number of patients who experienced the events; SAE = serious adverse event; TEAE = treatment-emergent adverse event.

6.25 The resubmission stated that no additional safety data were identified and did not present an updated ITC comparing the safety of NEMO to DUPI. The safety ITC from the previous submission is presented in Table 11.

Table 11: ITCs of NEMO 30 mg Q4W vs DUPI 300 mg Q2W: TEAEs, serious TEAEs and TEAEs leading to discontinuation (Safety population)[a]

	Intervention n/N (%)	Comparator n/N (%)	RR (95% CI)	RD (95% CI)
Any TEAEs				
NEMO 30 mg Q4W vs placebo				
ARCADIA 1	306/616 (49.7)	146/321 (45.5)	1.09 (0.95, 1.26)	0.04 (-0.03, 0.11)
ARCADIA 2	215/519 (41.4)	117/263 (44.5)	0.93 (0.79, 1.10)	-0.03 (-0.10, 0.04)
Study 114322	47/57 (82.5)	43/57 (76.8)	1.09 (0.90, 1.32)	0.07 (-0.08, 0.22)
ARCADIA CYCLO	71/137 (51.8)	70/137 (51.1)	1.01 (0.81, 1.28)	0.01 (-0.11, 0.13)
Pooled (REM)			1.04 (0.94, 1.15)	0.02 (-0.04, 0.07)
DUPI 300 mg Q2W vs placebo				
CAFÉ	77/107 (72.0)	75/108 (69.4)	1.04 (0.87, 1.23)	0.03 (-0.10, 0.15)
CHRONOS	97/110 (88.2)	266/315 (84.4)	1.04 (0.96, 1.14)	0.04 (-0.04, 0.11)
JADE COMPARE	121/242 (50.0)	70/131 (53.4)	0.94 (0.76, 1.15)	-0.03 (-0.14, 0.07)
Pooled (REM)			1.03 (0.96, 1.10)	0.02 (-0.04, 0.07)
Indirect comparison				
NEMO 30 mg Q4W (pooled) vs DUPI 300 mg Q2W (pooled)			1.01 (0.90, 1.13)	-0.01 (-0.10, 0.08)
Serious TEAEs				
NEMO 30 mg Q4W vs placebo				
ARCADIA 1	6/616 (1.0)	4/321 (1.2)	0.78 (0.22, 2.75)	-0.00 (-0.02, 0.01)
ARCADIA 2	13/519 (2.5)	3/263 (1.1)	2.20 (0.63, 7.64)	0.01 (-0.01, 0.03)
Study 114322	2/57 (3.5)	1/57 (1.8)	2.00 (0.187, 21.44)	0.02 (-0.04, 0.08)
ARCADIA CYCLO	2/137 (1.5)	2/137 (1.5)	1.00 (0.14, 7.00)	0.00 (-0.03, 0.03)
Pooled (REM)			1.32 (0.61, 2.83)	0.00 (-0.01, 0.01)
DUPI 300 mg Q2W vs placebo				
CAFÉ	2/107 (1.9)	2/108 (1.9)	1.01 (0.15, 7.04)	0.0 (-0.04, 0.04)
CHRONOS	4/110 (3.6)	16/315 (5.1)	0.72 (0.25, 2.10)	-0.01 (-0.06, 0.03)
JADE COMPARE	2/242 (0.8)	5/131 (3.8)	0.22 (0.04, 1.10)	-0.03 (-0.07, 0.01)
Pooled (REM)			0.56 (0.25, 1.27)	-0.02 (-0.04, 0.01)
Indirect comparison				
NEMO 30 mg Q4W (pooled) vs DUPI 300 mg Q2W (pooled)			2.36 (0.77, 7.21)	0.02 (-0.01, 0.05)
TEAEs leading to discontinuation				
NEMO 30 mg Q4W vs placebo				
ARCADIA 1	9/616 (1.5)	3/321 (0.9)	1.56 (0.43, 5.73)	0.01 (-0.01, 0.02)
ARCADIA 2	15/519 (2.9)	3/263 (1.1)	2.53 (0.74, 8.68)	0.02 (-0.00, 0.04)
Study 114322	2/57 (3.5)	4/57 (7.0)	0.50 (0.10, 2.62)	-0.04 (-0.12, 0.05)
ARCADIA CYCLO	2/137 (1.5)	3/137 (2.2)	0.67 (0.11, 3.93)	-0.01 (-0.04 0.02)
Pooled (REM)			1.30 (0.62, 2.66)	0.01 (0.00, 0.02)
DUPI 300 mg Q2W vs placebo				
CAFÉ	0/107	1/108 (0.9)		-0.01 (-0.03, 0.01)
CHRONOS	2/110 (1.8)	24/315 (7.6)	0.24 (0.06, 0.99)	**-0.06 (-0.10, -0.02)**
JADE COMPARE	8/242 (3.3)	5 /131(3.8)	0.87 (0.29, 2.59)	-0.01 (-0.05, 0.04)
Pooled (REM)			0.51 (0.21, 1.25)	-0.02 (-0.06, 0.01)
Indirect comparison				
NEMO 30 mg Q4W (pooled) vs DUPI 300 mg Q2W (pooled)			2.53 (0.80, 8.00)	0.03 (-0.00, 0.06)

Source: Table 2-88, p 215 of the previous submission.

CI = confidence interval; DUPI = dupilumab; ITC = indirect treatment comparison; Q2W = every 2 weeks; Q4W = every 4 weeks; RD = risk difference; REM = random effects model; RR = relative risk; TEAEs = treatment emergent adverse events

[a] Treatment exposure was 16 weeks for ARCADIA 1, ARCADIA 2, ARCADIA CYCLO, CAFÉ and COMPARE, 24 weeks for Study 114322, and 52 weeks for CHRONOS

Blue shading indicates data previously seen by the PBAC

Benefits/harms

6.26 A benefits and harms table is not presented as the resubmission made a claim of non-inferiority.

Clinical claim

6.27 The resubmission described NEMO as non-inferior in terms of effectiveness compared to DUPI. In the previous submission, the ITCs used to support the claim of non-inferior efficacy had several transitivity issues and indicated that NEMO may have inferior efficacy when compared to DUPI. The resubmission presented data that included patients who underwent an extended induction period with NEMO if they had an inadequate treatment response at Week 16 and included this in updated ITCs. This evidence demonstrated that an extended induction period resulted in more patients achieving an adequate response and that the total number of responders was similar to what is seen with DUPI at 16 weeks. However, the ESC noted that there were several issues with the analyses that impacted the reliability of the ITC results and considered that the claim of non-inferior effectiveness was not adequately supported. The data included from the ARCADIA LTE was single arm, open-label, and based on a subgroup determined *post-hoc* to consist of patients who did not respond at Week 16. The ESC noted that the ARCADIA LTE results did show a sustained response with NEMO out to 104 weeks; however, the dose regimen did not align with that in the TGA PI (see paragraph 6.13).

6.28 The resubmission described NEMO as non-inferior in terms of safety compared to DUPI. The ESC considered that this claim was not adequately supported as no additional comparative data were provided in the resubmission. Based on the data provided in the previous submission the PBAC considered the claim of non-inferior comparative safety to be uncertain, noting it was based on unanchored ITCs which were statistically underpowered and the selected safety outcomes in the ITCs did not capture individual AEs that may be important when comparing NEMO to DUPI (paragraph 6.48, nemolizumab PSD, July 2025 PBAC meeting). The resubmission presented extended safety data for patients receiving NEMO for up to 104 weeks. These data showed a low level of TEAEs leading to discontinuation, indicating that longer term use of NEMO is well tolerated.

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

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

Economic analysis

6.31 The resubmission presented a CMA comparing NEMO with DUPI for the treatment of patients aged 12 years or older with chronic severe AD.

6.32 The key components of the CMA are summarised in Table 12.

Table 12: Key components and assumptions of the cost-minimisation approach

Component	Claim or assumption
Therapeutic claim: effectiveness	Based on evidence presented in the resubmission, effectiveness was assumed to be non-inferior.
Therapeutic claim: safety	Based on evidence presented in the resubmission, safety was assumed to be non-inferior, but with fewer injection site reactions and patients with conjunctivitis.
Evidence base	Indirect comparison of nemolizumab with dupilumab. Based on data from the ARCADIA and ARCADIA LTE trials for the subgroup of patients who had severe AD, 74.1% of all responding NEMO patients had an EASI-50 response at Week 16 and 25.9% had an EASI-50 response at Week 24.
Equi-effective doses	Nemolizumab: an initial dose of 60 mg, followed by 30 mg Q4W for 16 weeks or 24 weeks, and 30 mg Q8W thereafter. Dupilumab: 600 mg SC injection as a loading dose, followed by 300 mg SC injection Q2W in adult patients and in adolescents ≥ 60 kg; 400 mg SC injection as a loading dose, followed by 200 mg SC injection Q2W in adolescents < 60 kg.
Direct medicine costs	The cost of nemolizumab per patient for 2 years of treatment was higher to account for a reduction in conjunctivitis in patients treated with nemolizumab compared to those treated with dupilumab.
Other costs or cost offsets	An additional specialist visit was included for slow responders to nemolizumab treatment. Offsets for a reduction in the adverse event of conjunctivitis was included.

Source: Table 3-1, pp72 of the resubmission.
AD = atopic dermatitis; EASI-50 = improvement of at least 50% from baseline in Eczema Area and Severity Index; NEMO = nemolizumab; Q2W = every 2 weeks; Q4W = every 4 weeks; Q8W = every 8 weeks; SC = subcutaneous
Blue shading represents data previously considered by the PBAC.

6.33 The equi-effective doses were estimated in the submission as:

- For adults and adolescents ≥ 60kg: NEMO at an initial dose of 60 mg (given as 2 x 30 mg subcutaneous [SC] injections at Week 0), followed by 30 mg SC injection Q4W until Week 16 for 74.1% of patients or Week 24 for 25.9% of patients (for slow responders), and 30 mg Q8W thereafter is equi-effective to dupilumab 600 mg SC injection as a loading dose followed by 300 mg SC injection every 2 weeks (Q2W).
- For adolescents < 60kg: NEMO at an initial dose of 60 mg (given as 2 x 30 mg SC injections at Week 0), followed by 30 mg SC injection Q4W until Week 16 for 74.1% of patients or Week 24 for 25.9% of patients (for slow responders), and 30 mg Q8W thereafter is equi-effective to DUPI 400 mg SC injection as a loading dose followed by 200 mg SC injection Q2W.

As the published AEMPs for the 200 mg and 300 mg strengths of DUPI are the same, the resubmission did not provide a split for adolescent/adults receiving treatment.

6.34 The equi-effective doses proposed in the resubmission were consistent with those requested in the original submission except for the inclusion of an extended induction period (additional 8 weeks) for NEMO in patients who do not respond adequately by Week 16. This aligned with the proposed changes to the TGA label for NEMO.

6.35 The ESC noted that the previously determined equi-effective doses for DUPI and UPA could be used to inform equi-effective doses for NEMO and UPA for the purpose of determining the lowest cost alternative therapy (paragraph 7.12, upadacitinib PSD, July 2021 PBAC meeting).

6.36 In the base case, the proportions of NEMO patients considered to respond at Week 16 (74.1%, 164 out of 221) and the slow responders (25.9%, 57 out of 221) were from the NEMO trials and the LTE study based on EASI-50 outcome in the subgroup of patients with severe AD. As discussed in the "Comparative effectiveness" section, the proportion of slow responders was an area of uncertainty. Based on the results of the EASI-50, NEMO best case scenario (i.e. when a higher proportion of patients respond at 24 weeks; Table 9), slow responders accounted for 92[15] out of 256[16] all responders, equal to 35.9% (vs. 25.9% [57/221] in the average case scenario) – see Sensitivity Analyses, Table 14.

6.37 The resubmission included one additional specialist visit (MBS item 105, $50.95) for those patients considered to be slow responders at Week 24 to determine eligibility for continuing treatment.

6.38 Consistent with the original submission, the CMA in the resubmission included cost offsets associated with management of conjunctivitis in patients treated with DUPI. The derivation of costs for treatment of conjunctivitis remained unchanged from previous submission, with relevant PBS and MBS costs updated to reflect current costs. Both submissions assumed that the incidence of eye complications during the first 16 weeks of treatment as reported in the clinical trials would be constant during the maintenance treatment period. Cost offsets associated with management of eye complications were uncertain. The ESC previously considered that cost offsets for conjunctivitis should not be included in the CMA (paragraph 6.51, nemolizumab PSD, July 2025 PBAC meeting). The inclusion of costs for treatment of conjunctivitis in patients receiving DUPI, however, had a minimal impact on the CMA result, given its relatively low cost ($0.73 per week) compared with the drug costs for DUPI (ex-manufacturer price of $402.47 per week).

6.39 The results of the CMA are presented in Table 13. The analysis was based on the published AEMP for DUPI.

[15] = 77.5% x 330 – 164, where 77.5% is the response rate in the severe population at Week 24 in the EASI-50, NEMO best case scenario, 330 is the number of patients with severe AD at baseline, and 164 is the number of responders at Week 16 (Table 8 and Table 9).
[16] = 77.5% x 330

Table 13: Results of the cost-minimisation approach using published prices

Component	Nemolizumab	Dupilumab
Ex-manufacturer price per script	$2,627.71 per 30 mg pen	$1,609.86 per 2 x 300/200 mg syringes[a]
No. of doses over 2 years	16.26 doses over 104 weeks (74.1% = 16 doses 25.9% = 17 doses)	53 doses over 104 weeks
No. of scripts over 2 years	16.26	26.5
Total medicines cost over 2 years	$42,723.70	$42,661.29
Cost of specialist visit for slow responders	$13.19	$0.00
Cost of managing eye complications	$0.00	$75.60
Total 2-year treatment cost	$42,736.89	$42,736.89

Source: Adapted from Table 3-4, p77 of the resubmission.
a. The published AEMPs for the 200 mg and 300 mg strengths of dupilumab are the same

6.40 The March 2026 pre-PBAC response stated that it would be willing to honour the price offer made in the July 2025 pre-PBAC response, which was a [redacted]% reduction to the proposed EMP. This would result in an EMP for NEMO of $[redacted] per 30 g pen.

6.41 Results of sensitivity analyses assuming a higher proportion of slow responders, changing cost offsets associated with management of conjunctivitis and excluding the additional specialist visit for NEMO non-responders are presented in Table 14. Overall, the impact of these changes was not substantial.

Table 14: Results of sensitivity analyses

Component	NEMO cost-minimised price	% change from base case
Base case ex-manufacturer price per 30 mg pen	**$2,627.71**	**–**
35.9% are slow responders (base case: 25.9%)	$2,611.32	-0.6%
Excluding conjunctivitis costs (base case: $75.60)	$2,623.06	-0.2%
Including conjunctivitis costs based on incidence over 16 weeks without extrapolation of incidence, i.e., $11.63 (base case: $75.60)	$2,623.78	-0.1%
Excluding additional specialist visit for NEMO slow responders	$2,628.52	+0.0%
Multivariate sensitivity analysis		
35.9% are slow responders + excluding conjunctivitis costs	$2,606.70	-0.8%

Source: Sensitivity analyses performed during the evaluation.
DUPI = dupilumab; NEMO = nemolizumab; RDI = relative dose intensity

Drug cost/patient/year

6.42 Using DPMQs, the drug cost/patient/dose for NEMO was $5,418.35 for the loading dose (60 mg) and $2,790.64 for the subsequent doses (30 mg Q4W, 30 mg Q8W). This results in a drug cost/patient/year for NEMO of $26,348 (16-week induction period) or $29,139 (24-week induction period) in Year 1 and $18,139 for each subsequent year.

6.43 The drug cost/patient/year for DUPI is $23,706 in Year 1 and $22,828 for each subsequent year.

6.44 Based on the CMA, over a two-year period and assuming 74.1% of NEMO patients respond at 16 weeks and 25.9% respond at 24 weeks, the total cost of NEMO using DPMQs is $45,210 compared to $46,534 for DUPI.

6.45 For patients who don't respond to treatment (i.e. receive induction treatment only) the cost using DPMQs is $22,162 for 24 weeks of NEMO treatment and $8,780 for 16 weeks of DUPI. The ESC noted that the cost for non-responders was substantially higher for NEMO patients.

Estimated PBS usage & financial implications

6.46 This resubmission was not considered by DUSC.

6.47 The resubmission utilised a market share approach to estimate the extent of use and financial impact of listing NEMO on the PBS for the treatment of severe AD. The existing market was defined as the existing PBS listed medicines for the treatment of severe AD (DUPI and UPA)[17]. The resubmission noted that the listing of NEMO (every 8 weeks) is expected to be cost saving due to less frequent dosing (continuing treatment phase is every 8 weeks) relative to the comparators (DUPI is every 3 weeks and UPA is daily) and the difference in the maximum quantity per dispensing.

6.48 Further, while the restriction does not prevent sequential use of treatments listed for severe AD, the resubmission reiterated that the PBAC has previously considered that the impact of allowing sequential treatment and switching between treatments was unlikely to have a significant financial impact (paragraph 3.5, lebrikizumab PSD, March 2024 PBAC meeting).

6.49 A summary of the data sources and parameter values used to estimate the utilisation and financial impacts associated with the proposed listing of NEMO for AD are shown in Table 15.

[17] While lebrikizumab has received a positive PBAC recommendation, it has not progressed to listing on the PBS and therefore has not been included.

Table 15: Key inputs for financial estimates

Data	Value	Source	Comment
Existing market			
Medicines	DUPI 200mg DUPI 300mg UPA 15mg UPA 30mg	All PBS listed medicines for severe AD	Unchanged.
Total scripts	PBS: 350,132 RPBS: 2,311	Services Australia Utilisation statistics for PBS items: 1 Jan – 31 Aug 2025	Based on updated figures. The growth rate is uncertain, as noted in para 6.50.
Growth rate	Decreasing from 12.32% in Year 1 to 8.26% in Year 6	DUPI July 2024 PSD, Table 6 extrapolated	Unchanged; however uncertain as the figures now apply to later years in the extrapolation and applies across a nine-year period.
Uptake rate	Increasing from [redacted]% in Year 1 to [redacted]% in Year 6	Sponsor assumption	The uptake rate has been reduced by [redacted]% from the previous submission. The uptake rate remains uncertain.
Script equivalence			
DUPI 200mg / 300mg NEMO 30mg x 2 - Initial	Existing: 5 Proposed: 3.26	Sponsor calculation	The existing number of scripts required for initial treatment is taken from the DUPI PI. The number of scripts for NEMO is weighted between the two responder groups (74.1% respond at 16 weeks, 25.9% respond at 24 weeks) which increases the number of initial scripts and reduces the continuing scripts.
DUPI 200mg / 300mg NEMO 30mg - Continuing	Existing: 22 Proposed: 9.74		
UPA 15mg / 30mg NEMO 30mg x 2 - Initial	Existing: 4 Proposed: 3.26		
UPA 15mg / 30mg NEMO 30mg - Continuing	Existing: 22 Proposed: 9.74		
Financial impact			
Published DPMQ	$5,418.35	NEMO 30 mg x 2- Initiating	-
Published DPMQ	$2,790.64	NEMO 30 mg - Continuing	
Patient copayment	$24.94 PBS $6.08 RPBS	12291X, 12292Y - DUPI 12827D, 12828E, 12829F, 12831H, 12835M, 12836N - UPA	-

Source: The financial estimates from the resubmission: 2e. Scripts - market; 3a. Scripts - proposed; 3b. Impact - proposed (pub).
AD = Atopic dermatitis; AEMP = Approved ex-manufacturer price; DPMQ = Dispensed price maximum quantity; DUPI = Dupilumab; NEMO = Nemolizumab; PBAC = Pharmaceutical Benefits Advisory Committee; PBS = Pharmaceutical Benefits Scheme; PI = Product Information; PSD = Public summary document; RPBS = Repatriation Pharmaceutical Benefits Schedule; UPA = Upadacitinib.

6.50 The resubmission assumed a listing of NEMO in 2027 and therefore estimated the market for the period 2027-2032. The resubmission was based on the script volumes for DUPI and UPA for the first eight months of 2025, the most recent data available at the time of resubmission. These script volumes were annualised by factoring the actual volumes to 12 months (divide the scripts by 8 and multiply by 12). This approach does not account for the seasonal increase that occurs in many PBS medicines in the final months of each year.

6.51 While UPA and NEMO have PBS treatment regimens that are divided into initial and continuing treatment phases, the DUPI listing does not have this distinction. This means that the PBS script volumes for DUPI are contained in a single PBS item code for each of the 200 mg and the 300 mg doses. To facilitate the script substitution to determine the cost of listing NEMO on the PBS, the resubmission split the overall DUPI script volumes into initial and continuing scripts. The split was based on the number

of DUPI initial scripts required in a two-year period[18] (5/27 scripts or 18.52%). This was unchanged from the previous submission. In July 2025, the ESC noted that this split did not account for patients who commence DUPI and do not continue treatment (paragraph 6.61, nemolizumab PSD, July 2025 PBAC meeting). Due to the loading dose associated with DUPI, the ESC also previously noted that the financial estimates were very sensitive to changes in the initial/continuing treatment split. The impact of applying the UPA initial/continuing treatment split to DUPI is presented in Table 16.

Table 16 Impact of initial / continuing split

Published PBS/RPBS cost	2027	2028	2029	2030	2031	2032
Original initial split (18.52%)	$[redacted][1]	$[redacted][2]	$[redacted][2]	$[redacted][3]	$[redacted][3]	$[redacted][4]
UPA initial split (23.88%)	$[redacted][1]	$[redacted][2]	$[redacted][2]	$[redacted][3]	$[redacted][3]	$[redacted][4]

Source: Constructed during the evaluation from resubmission data
PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Schedule; UPA = Upadacitinib.
The redacted values correspond to the following ranges:
[1] *$60 million to < $70 million*
[2] *$100 million to < $200 million*
[3] *$200 million to < $300 million*
[4] *$300 million to < $400 million*

6.52 As the resubmission included an extended induction for slower responders, the number of NEMO initial scripts was calculated from the weighted average number of scripts required by both responder groups. The continuing scripts were calculated by subtracting the initial scripts from the expected total number of scripts received in a 2-year period as shown in Table 17.

Table 17: Weighted average scripts

Treatment option	Proportion	Initial	Continuing	Total
Standard 16-week induction	74.1%	3	10	13
Extended 24-week induction	25.9%	4	9	13
Weighted scripts		3.26	9.74	13

Source: The financial estimates from the resubmission: 3a. Scripts - proposed.

6.53 While this approach aligns with the CMA period and provides a valid comparison over the first two years of treatment, it overestimates the number scripts required over a patient's full treatment duration. Initial treatment requires more scripts than continuing treatment, so including an initial treatment in each of the subsequent years overestimated the total number of scripts required.

6.54 The resubmission's financial estimates are shown in

6.55 Table 18.

[18] The duration of the CMA comparison.

Table 18: Estimated use and financial implications – published

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Scripts - proposed medicine(s)						
NEMO 30 mg x 2 - initiating	[redacted][1]	[redacted][2]	[redacted][3]	[redacted][3]	[redacted][3]	[redacted][4]
NEMO 30 mg - continuing	[redacted][3]	[redacted][4]	[redacted][5]	[redacted][6]	[redacted][7]	[redacted][8]
Total scripts	[redacted][3]	[redacted][5]	[redacted][6]	[redacted][8]	[redacted][9]	[redacted][10]
Net financial impact of NEMO						
PBS/RPBS less copayments	$[redacted][11]	$[redacted][12]	$[redacted][12]	$[redacted][13]	$[redacted][13]	$[redacted][14]
Scripts - affected medicine(s)						
12291X - DUPI 200 mg	-[redacted][1]	-[redacted][1]	-[redacted][2]	-[redacted][2]	-[redacted][2]	-[redacted][3]
12292Y - DUPI 300 mg	-[redacted][5]	-[redacted][7]	-[redacted][9]	-[redacted][15]	-[redacted][15]	-[redacted][15]
12828E - UPA 15 mg - Initiating	-[redacted][1]	-[redacted][1]	-[redacted][1]	-[redacted][1]	-[redacted][1]	-[redacted][1]
12831H - UPA 15 mg - Continuing	-[redacted][1]	-[redacted][1]	-[redacted][1]	-[redacted][2]	-[redacted][2]	-[redacted][2]
12835M - UPA 15 mg - Continuing	-[redacted][16]	-[redacted][16]	-[redacted][16]	-[redacted][16]	-[redacted][16]	-[redacted][16]
12836N - UPA 30 mg - Initiating	-[redacted][16]	-[redacted][16]	-[redacted][16]	-[redacted][16]	-[redacted][16]	-[redacted][1]
12829F - UPA 30 mg - Continuing	-[redacted][1]	-[redacted][1]	-[redacted][2]	-[redacted][2]	-[redacted][2]	-[redacted][3]
12827D - UPA 30 mg - Continuing	-[redacted][16]	-[redacted][1]	-[redacted][1]	-[redacted][1]	-[redacted][1]	-[redacted][1]
Total scripts	-[redacted][5]	-[redacted][8]	-[redacted][19]	-[redacted][15]	-[redacted][15]	-[redacted][15]
Net financial impact of affected medicine(s)						
PBS/RPBS less copayments	-$[redacted][11]	-$[redacted][12]	-$[redacted][12]	-$[redacted][13]	-$[redacted][13]	-$[redacted][14]
Net financial impact						
Net cost to PBS/RPBS	**-$[redacted][17]**	**-$[redacted][17]**	**-$[redacted][17]**	**-$[redacted][17]**	**-$[redacted][17]**	**-$[redacted][18]**
July 2025 submission						
Total NEMO scripts	[redacted][4]	[redacted][5]	[redacted][7]	[redacted][9]	[redacted][19]	[redacted][20]
Cost of NEMO to PBS/ RPBS less copayments	$[redacted][22]	$[redacted][12]	$[redacted][12]	$[redacted][13]	$[redacted][14]	$[redacted][14]
Total DUPI and UPA scripts	-[redacted][6]	-[redacted][9]	-[redacted][15]	-[redacted][15]	-[redacted][15]	-[redacted][21]
Cost offsets of DUPI and UPA to PBS/RPBS less copayments	-$[redacted][22]	-$[redacted][12]	-$[redacted][12]	-$[redacted][13]	-$[redacted][14]	-$[redacted][14]
Net cost of NEMO to PBS/RPBS	-$[redacted][17]	-$[redacted][17]	-$[redacted][17]	-$[redacted][17]	-$[redacted][17]	-$[redacted][18]

Source: The financial estimates from the resubmission: 3a. Scripts - proposed; 3b. Impact - proposed (pub); 4a. Scripts - affected; 4b. Impact - affected (pub); 5. Impact - net.

DUPI = Dupilumab; NEMO = Nemolizumab; PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Schedule; UPA = Upadacitinib.

Note: Blue shading indicates data previously seen by the PBAC in July 2025.

The redacted values correspond to the following ranges:

[1] *500 to < 5,000*

[2] *5,000 to < 10,000*

[3] *10,000 to < 20,000*

[4] *20,000 to < 30,000*

[5] *30,000 to < 40,000*
[6] *40,000 to < 50,000*
[7] *50,000 to < 60,000*
[8] *60,000 to < 70,000*
[9] *70,000 to < 80,000*
[10] *80,000 to < 90,000*
[11] *$60 million to < $70 million*
[12] *$100 million to < $200 million*
[13] *$200 million to < $300 million*
[14] *$300 million to < $400 million*
[15] *100,000 to < 200,000*
[16] *< 500*
[17] *$0 to < $10 million*
[18] *$10 million to < $20 million*
[19] *90,000 to < 100,000*
[20] *100,000 to < 200,000*
[21] *200,000 to < 300,000*
[22] *$70 million to < $80 million*

6.56 The resubmission estimated that the cost saving to the PBS/RPBS of listing NEMO would be $0 to < $10 million in Year 1 increasing to $10 million to < $20 million in Year 6 and totalling $40 million to < $50 million over the first 6 six years. The cost saving was due NEMO requiring fewer prescriptions per year than DUPI and UPA.

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

7 PBAC Outcome

7.1 The PBAC recommended the listing of nemolizumab (NEMO) for the treatment of patients with severe atopic dermatitis (AD) affecting the whole body, face, and/or hands. The PBAC, noting the additional data presented in the resubmission that included treatment with an extended NEMO induction period, considered the submission's clinical claim of non-inferior effectiveness of NEMO to dupilumab (DUPI) was adequately supported. The PBAC's recommendation was based on, among other matters, its assessment that the cost effectiveness of NEMO would be acceptable if it were cost minimised to the least costly alternative therapy of DUPI or upadacitinib (UPA). The PBAC advised that NEMO should join the Risk Sharing Arrangement (RSA) for severe AD with no increase to the expenditure caps.

7.2 The PBAC noted the sponsor hearing which highlighted safety benefits associated with NEMO, and the inputs received again from the Australasian College of Dermatologists (ACD), the Australasian Society of Clinical Immunology and Allergy (ASCIA) and a joint submission between Allergy & Anaphylaxis Australia, and the National Allergy Council, all of which supported the listing of NEMO on the PBS for AD. The PBAC acknowledged that there is a need for alternative treatments with different mechanisms of action to be available on the PBS.

7.3 The PBAC noted that the TGA Delegate's Overview supported an addition to the recommended dosing of NEMO to allow for the extended induction period (see paragraph 2.2).

7.4 The PBAC recalled that in July 2025 it had considered that NEMO was likely inferior in terms of comparative effectiveness compared to DUPI, based on 16 weeks treatment for both therapies. The resubmission presented additional analyses of the long-term extension phases of the ARCADIA 1 and ARCADIA 2 trials to support an extended induction period to allow patients an additional 8 weeks of four weekly (Q4W) NEMO treatment if they had not responded at Week 16. The PBAC noted that an additional 30.1% of NEMO patients had at least a 75% improvement in Eczema Area and Severy Index (EASI-75) response and 9.6% more had a positive Investigators Global Assessment (IGA) response after 24 weeks of induction. Further, the proportion of patients meeting the EASI-50 response criteria after 24 weeks, which is a component of the proposed PBS restriction criteria, was similar for NEMO patients after 24 weeks of treatment (67.1%) and DUPI after 16 weeks of treatment (67.0%). Despite the *post hoc* nature of the comparison at 24 weeks (see paragraph 6.9), the PBAC considered that overall, NEMO (with a 16 to 24 week induction period) was likely non-inferior compared to DUPI (with at 16 week induction period) in terms of efficacy.

7.5 The PBAC noted that the resubmission again described NEMO as non-inferior compared to DUPI in terms of safety. The PBAC recalled that it previously considered that this conclusion was uncertain as a number of the indirect treatment comparisons were statistically underpowered. The PBAC noted that although the resubmission did not present any additional comparative data, the extended safety data from the ARCADIA LTE study indicated that NEMO was well tolerated for up to 104 weeks. Noting the additional data and the advice received in the sponsor hearing regarding the safety profile of NEMO (see paragraph 6.1), the PBAC considered that on balance, NEMO was likely non-inferior compared to DUPI in terms of safety.

7.6 The PBAC considered that the approach for the CMA as presented in the resubmission was reasonable, but that the cost offsets associated with conjunctivitis should be removed (see paragraph 6.38) consistent with its view that the treatments are non-inferior in terms of safety, and the proportion of responding patients treated with 24 weeks of treatment, rather than at 16 weeks, should be increased form 25.9% to 35.9% (see paragraph 6.36).

7.7 The PBAC noted that the equi-effective doses were:

- NEMO: 60 mg initial loading dose, followed by 30 mg Q4W until Week 16 for 64.1% of patients or Week 24 for 35.9% of patients; then 30 mg Q8W DUPI (adults/adolescents ≥ 60 kg): 600 mg loading dose, followed by 300 mg Q2W
- DUPI (adolescents < 60 kg): 400 mg loading dose, followed by 200 mg Q2W

7.8 The previously determined equi-effective doses of DUPI and UPA could be used to inform the equi-effective doses of NEMO and UPA for the purpose of determining the

lowest cost alternative therapy (paragraph 7.12, upadacitinib PSD, July 2021 PBAC meeting).

7.9 The PBAC noted that the March 2026 pre-PBAC response stated that it would honour the [redacted]% price reduction proposed in the July 2025 pre-PBAC response.

7.10 The PBAC noted that the cost of induction (i.e. the first 16 to 24 weeks) for NEMO was substantially higher than that of DUPI (over 16 weeks) (see paragraph 6.45), but that this was offset by the dosing schedule of the two drugs in the maintenance phase (Q8W for NEMO and Q2W for DUPI), which resulted in lower ongoing treatment costs for NEMO.

7.11 The PBAC noted that the resubmission presented revised utilisation and financial estimates in which the uptake of NEMO was reduced by [redacted]%. The PBAC considered that this change was reasonable. The PBAC noted that NEMO was estimated to result in cost savings to the PBS/RPBS due to NEMO requiring fewer doses per year than DUPI and upadacitinib (UPA), resulting in lower costs associated with the wholesaler mark-up and administration, handline and infrastructure (AHI) fees.

7.12 The PBAC noted that there was an RSA for DUPI and UPA for the treatment of severe AD. The PBAC advised that NEMO should join the RSA with no increases to the expenditure caps.

7.13 In terms of the proposed restrictions, the PBAC considered that the changes suggested by the Secretariat were appropriate. The PBAC also advised that the clinical criterion in the grandfather clause: "Patient must not be experiencing an inadequate response to…", should be amended to "Patient must have achieved an adequate response to…" to remove the double negative and improve clarity.

7.14 The PBAC recommended that NEMO should not be treated as interchangeable with any other drugs.

7.15 The PBAC advised that NEMO is not suitable for prescribing by nurse practitioners.

7.16 The PBAC advised that NEMO should not be exempt from the Early Supply Rule.

7.17 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because NEMO is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over DUPI, 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.

7.18 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:
Recommended

8 Recommended listing

8.1 Add new item:

Initial

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
NEMOLIZUMAB					
nemolizumab 30 mg injection [1 chamber] (&) inert substance diluent [1 chamber], 1 dual chamber pen device	NEW	2	2	2	Nemluvio

Concept ID	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)
	Prescriber type: ☒ Medical Practitioners
	Benefit type: ☒ Authority Required (Telephone/Online PBS Authorities System)
	Prescribing rule level:
	Administrative Advice: No increase in the maximum quantity or number of units may be authorised.
	Administrative Advice: No increase in the maximum number of repeats may be authorised.
	Administrative Advice: Special Pricing Arrangements apply.
	Administrative Advice: The Eczema Area and Severity Index (EASI) referenced in this restriction is that described in the following literature publications: Chalmers JR et al. Report from the third international consensus meeting to harmonise core outcome measures for atopic eczema/dermatitis clinical trials (HOME). *British Journal of Dermatology* 2014 December;171(6):1318-25. Schmitt J et al. HOME initiative collaborators. The Harmonising Outcome Measures for Eczema (HOME) statement to assess clinical signs of atopic eczema in trials. *The Journal of Allergy and Clinical Immunology* 2014 October;134(4):800-7
	Administrative Advice: Instructions on the use of the Dermatology Life Quality Index and copyright details can be found here: https://www.cardiff.ac.uk/medicine/resources/quality-of-life-questionnaires/dermatology-life-quality-index
	Administrative Advice: The Physician's Global Assessment (5-point scale) referenced in this restriction is that described in the following literature publication: Fatumura M et al. A systematic review of Investigator Global Assessment (IGA) in atopic dermatitis (AD) trials: Many options, no standards Journal of the American Academy of Dermatology 2016; 674(2): 288-94 The overall appearance of dermatitis lesions is rated as 4 (severe) if the lesions are best described as featuring: deep/dark red erythema, with marked and extensive induration/papulation; excoriation and oozing/crusting are present.
	Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.
	Restriction Summary [new1] / Treatment of Concept: [new1A]
	Indication: Chronic severe atopic dermatitis
	Treatment Phase: Initial treatment of the whole body

	Clinical criteria:
	Patient must have a Physicians Global Assessment (PGA) (5-point scale) baseline score of at least 4 as evidence of severe disease despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days
	AND
	Clinical criteria:
	Patient must have an Eczema Area and Severity Index (EASI) baseline score of at least 20 despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days
	AND
	Clinical criteria:
	Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days
	AND
	Clinical criteria:
	The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands
	AND
	Clinical criteria:
	Patient must not have experienced an inadequate response to this biological medicine in this PBS indication
	AND
	Clinical criteria:
	The treatment must be the sole PBS-subsidised biological medicine for this PBS indication
	Treatment criteria:
	Must be treated by a dermatologist; or
	Must be treated by a clinical immunologist
	Population criteria:
	Patient must be 12 years of age or older
	Prescribing Instructions: State each of the qualifying (i) PGA, (ii) EASI and (iii) DLQI scores in the authority application. Acceptable scores can be: (a) current scores; or (b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication. The EASI and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records. Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled in the patient's medical records.
	Prescribing Instructions: At the time of assessment of response, i.e., within 16 weeks of initial treatment, if adequate response hasn't been achieved, the prescriber can apply for an extended induction treatment (up to further 8 weeks of therapy) where there has been a partial response and the prescriber considers that extended induction doses could result in achieving adequate response.

	Restriction Summary [new2] / Treatment of Concept: [new2A]
	Indication: Chronic severe atopic dermatitis
	Treatment Phase: Initial treatment of the face and/or hands
	Clinical criteria:
	The condition must have at least 2 of the following Eczema Area and Severity Index (EASI) symptom sub-scores for erythema, oedema/papulation, excoriation, lichenification rated as severe despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days; or
	The condition must have affected at least 30% of the face/hands surface area despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days
	AND
	Clinical criteria:
	Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days
	AND
	Clinical criteria:
	The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands
	AND
	Clinical criteria:
	The treatment must be the sole PBS-subsidised biological medicine for this PBS indication
	AND
	Clinical criteria:
	Patient must not have experienced an inadequate response to this biological medicine in this PBS indication
	Treatment criteria:
	Must be treated by a dermatologist; or
	Must be treated by a clinical immunologist
	Population criteria:
	Patient must be 12 years of age or older
	Prescribing Instructions: State each of the 4 Eczema Area and Severity Index (EASI) symptom sub-score ratings (0 = none, 1 = mild, 2 = moderate, 3 = severe) for: (i) erythema, (ii) oedema/papulation, (iii) excoriation, (iv) lichenification Acceptable scores can be: (a) current scores; or (b) past scores, including those previously quoted in a PBS authority application for another drug listed for this indication. State the percentage face/hand surface area affected by the condition (must be at least 30%) where EASI symptom sub-scores are not provided. This percentage surface area can also be stated in addition to the EASI symptom sub-scores. The EASI/percentage surface area and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records. Document the details of the medium to high potency topical corticosteroids (or calcineurin inhibitors) initially trialled are in the patient's medical records.

	Prescribing Instructions: At the time of assessment of response, i.e., within 16 weeks of initial treatment, if adequate response hasn't been achieved, the prescriber can apply for an extended induction treatment (up to further 8 weeks of therapy) where there has been a partial response and the prescriber considers that extended induction doses could result in achieving adequate response.

Extended induction restriction

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
NEMOLIZUMAB					
nemolizumab 30 mg injection [1 chamber] (&) inert substance diluent [1 chamber], 1 dual chamber pen device	NEW	2	2	0	Nemluvio

Concept ID	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)
	Prescriber type: ☒ Medical Practitioners
	Benefit type: ☒ Authority Required (Telephone/Online PBS Authorities System)
	Prescribing rule level:
	Administrative Advice: No increase in the maximum quantity or number of units may be authorised.
	Administrative Advice: No increase in the maximum number of repeats may be authorised.
	Administrative Advice: Special Pricing Arrangements apply.
	Administrative Advice: The Eczema Area and Severity Index (EASI) referenced in this restriction is that described in the following literature publications: Chalmers JR et al. Report from the third international consensus meeting to harmonise core outcome measures for atopic eczema/dermatitis clinical trials (HOME). *British Journal of Dermatology* 2014 December;171(6):1318-25. Schmitt J et al. HOME initiative collaborators. The Harmonising Outcome Measures for Eczema (HOME) statement to assess clinical signs of atopic eczema in trials. *The Journal of Allergy and Clinical Immunology* 2014 October;134(4):800-7
	Administrative Advice: Instructions on the use of the Dermatology Life Quality Index and copyright details can be found here: https://www.cardiff.ac.uk/medicine/resources/quality-of-life-questionnaires/dermatology-life-quality-index
	Administrative Advice: The Physician's Global Assessment (5-point scale) referenced in this restriction is that described in the following literature publication: Fatumura M et al. A systematic review of Investigator Global Assessment (IGA) in atopic dermatitis (AD) trials: Many options, no standards Journal of the American Academy of Dermatology 2016; 674(2): 288-94 The overall appearance of dermatitis lesions is rated as 4 (severe) if the lesions are best described as featuring: deep/dark red erythema, with marked and extensive induration/papulation; excoriation and oozing/crusting are present.
	Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.
	Restriction Summary [new3] / Treatment of Concept: [new3A]
	Indication: Chronic severe atopic dermatitis

	Treatment Phase: Extended induction treatment (further 8 weeks of initial treatment of the whole body or the face and/or hands)
	Clinical criteria:
	Patient must have received PBS-subsidised treatment with this biological medicine for the treatment of chronic severe atopic dermatitis under the initial treatment or grandfather treatment phase of the whole body or the face and/or hands
	AND
	Clinical criteria:
	Patient must not be undergoing any of the following: (i) commencing treatment through this treatment phase listing, (ii) treatment accessed through this treatment phase more than once;
	AND
	Clinical criteria:
	Patient must not have achieved an adequate response after 16 weeks of treatment with this drug for this PBS indication;
	AND
	Clinical criteria:
	The treatment must be the sole PBS-subsidised biological medicine for this PBS indication
	Treatment criteria:
	Must be treated by a dermatologist; or
	Must be treated by a clinical immunologist
	Population criteria:
	Patient must be 12 years of age or older
	Prescribing Instructions: For the purposes of this restriction, an adequate response to treatment of the face/hands is defined as: (a) (i) A rating of either mild (1) to none (0) on at least 3 of the assessments of erythema, oedema/papulation, excoriation and lichenification mentioned in the Eczema Area and Severity Index (EASI); or (ii) At least a 75% reduction in the skin area affected by this condition compared to baseline; and (b) An improvement in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline Document each qualifying response measure in the patient's medical records for PBS compliance auditing purposes
	Prescribing Instructions: For the purposes of this restriction, an adequate response to treatment of whole body is defined as: (a) An improvement/maintenance in the Eczema Area and Severity Index (EASI) score of at least 50% compared to baseline; and (b) An improvement/maintenance in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline State each of the current EASI and DLQI scores for this authority application.
	Prescribing Instructions: Prescriber must only apply for this treatment phase if the patient has had a partial response to treatment and the prescriber considers that further induction treatment (further 8 weeks of therapy) with this drug is likely to result in an adequate response.
	Prescribing Instructions: A second assessment of response must be conducted between 24 to 28 weeks from the first administered dose of this drug to determine the patient's eligibility for continuing treatment. Where an assessment is not undertaken, the patient will not be eligible for ongoing treatment.

Continuing

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands

NEMOLIZUMAB					
nemolizumab 30 mg injection [1 chamber] (&) inert substance diluent [1 chamber], 1 dual chamber pen device	NEW	1	1	2	Nemluvio

Concept ID	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)
	Prescriber type: ☒ Medical Practitioners
	Benefit type: ☒ Authority Required (Telephone/Online PBS Authorities System)
	Prescribing rule level:
	Administrative Advice: No increase in the maximum quantity or number of units may be authorised.
	Administrative Advice: No increase in the maximum number of repeats may be authorised.
	Administrative Advice: Special Pricing Arrangements apply.
	Administrative Advice: The Eczema Area and Severity Index (EASI) referenced in this restriction is that described in the following literature publications: Chalmers JR et al. Report from the third international consensus meeting to harmonise core outcome measures for atopic eczema/dermatitis clinical trials (HOME). *British Journal of Dermatology* 2014 December;171(6):1318-25. Schmitt J et al. HOME initiative collaborators. The Harmonising Outcome Measures for Eczema (HOME) statement to assess clinical signs of atopic eczema in trials. *The Journal of Allergy and Clinical Immunology* 2014 October;134(4):800-7
	Administrative Advice: Instructions on the use of the Dermatology Life Quality Index and copyright details can be found here: https://www.cardiff.ac.uk/medicine/resources/quality-of-life-questionnaires/dermatology-life-quality-index
	Administrative Advice: The Physician's Global Assessment (5-point scale) referenced in this restriction is that described in the following literature publication: Fatumura M et al. A systematic review of Investigator Global Assessment (IGA) in atopic dermatitis (AD) trials: Many options, no standards Journal of the American Academy of Dermatology 2016; 674(2): 288-94 The overall appearance of dermatitis lesions is rated as 4 (severe) if the lesions are best described as featuring: deep/dark red erythema, with marked and extensive induration/papulation; excoriation and oozing/crusting are present.
	Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.
	Restriction Summary [new4] / Treatment of Concept: [new4A]
	Indication: Chronic severe atopic dermatitis
	Treatment Phase: Continuing or resuming treatment of the whole body
	Clinical criteria:
	Patient must have received PBS-subsidised treatment with this biological medicine for the treatment of chronic severe atopic dermatitis affecting the whole body
	AND
	Clinical criteria:
	Patient must have achieved an adequate response prior to this first continuing treatment authority application; or

	Patient must have maintained an adequate response to their most recent course of PBS-subsidised treatment with this biological medicine for this PBS indication if this is the second or subsequent Continuing treatment authority application; or
	Patient must have temporarily ceased treatment for reasons other than lack of response (e.g. family planning, vaccination with live vaccines, adverse-effect investigation), thereby being unable to achieve/maintain an adequate response immediately prior to this authority application
	AND
	Clinical criteria:
	The treatment must be the sole PBS-subsidised biological medicine for this PBS indication
	Treatment criteria:
	Must be treated by a dermatologist; or
	Must be treated by a clinical immunologist
	Prescribing Instructions: For the purposes of this restriction, an adequate response to treatment of the whole body is defined as: (a) An improvement/maintenance in the Eczema Area and Severity Index (EASI) score of at least 50% compared to baseline; and (b) An improvement/maintenance in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline Where an initial baseline (post-topical corticosteroid, pre-biological medicine) DLQI score was not measured for a patient who had commenced treatment through a clinical trial, early access program or through private, non-PBS-subsidised supply, an absence of worsening in the current DLQI score compared to that measured at the time of the 'Grandfather listing' authority application will suffice as an adequate response for requirement (b) above. State each of the current EASI and DLQI scores for this authority application.
	Restriction Summary [new5] / Treatment of Concept: [new5A]
	Indication: Chronic severe atopic dermatitis
	Treatment Phase: Continuing or resuming treatment of the face and/or hands
	Clinical criteria:
	Patient must have received PBS-subsidised treatment with this biological medicine for the treatment of chronic severe atopic dermatitis affecting the face/hands
	AND
	Clinical criteria:
	Patient must have achieved an adequate response prior to this first continuing treatment authority application; or
	Patient must have maintained an adequate response to their most recent course of PBS-subsidised treatment with this biological medicine for this PBS indication if this is the second or subsequent Continuing treatment authority application; or
	Patient must have temporarily ceased treatment for reasons other than lack of response (e.g. family planning, vaccination with live vaccines, adverse-effect investigation), thereby being unable to achieve/maintain an adequate response immediately prior to this authority application
	AND
	Clinical criteria:
	The treatment must be the sole PBS-subsidised biological medicine for this PBS indication
	Treatment criteria:
	Must be treated by a dermatologist; or

	Must be treated by a clinical immunologist
	Prescribing Instructions: For the purposes of this restriction, an adequate response to treatment of the face/hands is defined as: (a) (i) A rating of either mild (1) to none (0) on at least 3 of the assessments of erythema, oedema/papulation, excoriation and lichenification mentioned in the Eczema Area and Severity Index (EASI); or (ii) At least a 75% reduction in the skin area affected by this condition compared to baseline; and (b) An improvement in Dermatology Life Quality Index (DLQI) score of at least 4 points compared to baseline. Where an initial baseline (post-topical corticosteroid, pre-biological medicine) DLQI score was not measured for a patient who had commenced treatment through a clinical trial, early access program or through private, non-PBS-subsidised supply, an absence of worsening in the current DLQI score compared to that measured at the time of the 'Grandfather listing' authority application will suffice as an adequate response for requirement (b) above. State the current EASI ratings or the percentage of face/hand surface area affected by the condition. Also state the current DLQI score for this authority application.

Grandfather treatment

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
NEMOLIZUMAB					
nemolizumab 30 mg injection [1 chamber] (&) inert substance diluent [1 chamber], 1 dual chamber pen device	NEW	1	1	3	Nemluvio

Concept ID	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)
	Prescriber type: ☒ Medical Practitioners
	Benefit type: ☒ Authority Required (Telephone/Online PBS Authorities System)
	Prescribing rule level:
	Administrative Advice: No increase in the maximum quantity or number of units may be authorised.
	Administrative Advice: No increase in the maximum number of repeats may be authorised.
	Administrative Advice: Special Pricing Arrangements apply.
	Administrative Advice: The Eczema Area and Severity Index (EASI) referenced in this restriction is that described in the following literature publications: Chalmers JR et al. Report from the third international consensus meeting to harmonise core outcome measures for atopic eczema/dermatitis clinical trials (HOME). *British Journal of Dermatology* 2014 December;171(6):1318-25. Schmitt J et al. HOME initiative collaborators. The Harmonising Outcome Measures for Eczema (HOME) statement to assess clinical signs of atopic eczema in trials. *The Journal of Allergy and Clinical Immunology* 2014 October;134(4):800-7
	Administrative Advice: Instructions on the use of the Dermatology Life Quality Index and copyright details can be found here: https://www.cardiff.ac.uk/medicine/resources/quality-of-life-questionnaires/dermatology-life-quality-index
	Administrative Advice:

	The Physician's Global Assessment (5-point scale) referenced in this restriction is that described in the following literature publication: Fatumura M et al. A systematic review of Investigator Global Assessment (IGA) in atopic dermatitis (AD) trials: Many options, no standards Journal of the American Academy of Dermatology 2016; 674(2): 288-94 The overall appearance of dermatitis lesions is rated as 4 (severe) if the lesions are best described as featuring: deep/dark red erythema, with marked and extensive induration/papulation; excoriation and oozing/crusting are present.
	Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.
	Restriction Summary [new6] / Treatment of Concept: [new6A]
	Indication: Chronic severe atopic dermatitis
	Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment – 'Grandfather' arrangements (whole body)
	Clinical criteria:
	Patient must have been receiving non-PBS-subsidised treatment with this drug for this condition prior to [date of listing]
	AND
	Clinical criteria:
	Patient must have had an Eczema Area and Severity Index (EASI) baseline score of at least 20 despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days prior to commencing non-PBS-subsidised therapy with this biological medicine
	AND
	Clinical criteria:
	Patient must have had a Physicians Global Assessment (PGA) baseline score of at least 4 as evidence of severe disease despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days prior to commencing non-PBS-subsidised therapy with this biological medicine
	AND
	Clinical criteria:
	Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, prior to having commenced non-PBS-subsidised therapy with this biological medicine; or
	Patient must have, where the above baseline DLQI was not recorded in the patient's medical records, a current age-appropriate DLQI score (of any value) measured
	AND
	Clinical criteria:
	The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands, prior to commencing non-PBS-subsidised therapy with this biological medicine
	AND
	Clinical criteria:
	Patient must have achieved an adequate response to current non-PBS-subsidised therapy with this biological medicine, if they have received at least 16 weeks of therapy (or 24 weeks of therapy in the case of slow responders).
	AND
	Clinical criteria:

	The treatment must be the sole PBS-subsidised biological medicine for this PBS indication
	Treatment criteria:
	Must be treated by a dermatologist; or
	Must be treated by a clinical immunologist
	Population criteria:
	Patient must be 12 years of age or older
	Prescribing Instructions: State each of the qualifying PGA, EASI and DLQI scores in the authority application. The name/s of the medium to high potency topical corticosteroids trialled prior to commencing treatment with this biological medicine must be documented in the patient's medical records. The EASI and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records.
	Prescribing Instructions: A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under one of the following: (i) Continuing treatment, where there has been an adequate response to treatment (ii) Extended induction treatment (up to a further 8 weeks of therapy), where the patient has received 16 weeks of therapy, achieved a partial response and the prescriber considers that extended induction doses could result in achieving adequate response.
	Prescribing Instructions: This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.
	Restriction Summary [new7] / Treatment of Concept: [new7A]
	Indication: Chronic severe atopic dermatitis
	Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment – 'Grandfather' arrangements (face and/or hands)
	Clinical criteria:
	Patient must have been receiving non-PBS-subsidised treatment with this drug for this condition prior to [date of listing]
	AND
	Clinical criteria:
	The condition must have had at least 2 of the following Eczema Area and Severity Index (EASI) symptom sub-scores for erythema, oedema/papulation, excoriation, lichenification rated as severe despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, prior to commencing non-PBS-subsidised therapy with this biological medicine; or
	The condition must have affected at least 30% of the face/hands surface area despite treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, prior to commencing non-PBS-subsidised therapy with this biological medicine
	AND
	Clinical criteria:
	Patient must have an age appropriate Dermatology Life Quality Index (DLQI) baseline score (of any value) measured following treatment with daily topical therapy (corticosteroid of medium to high potency/calcineurin inhibitor), for at least 28 days, prior to commencing non-PBS-subsidised therapy with this biological medicine; or
	Patient must have, where the above baseline DLQI was not recorded in the patient's medical records, a current age-appropriate DLQI score (of any value) measured
	AND
	Clinical criteria:

	The condition must have had lesions for at least 6 months from the time of the initial diagnosis of chronic severe atopic dermatitis affecting either of: (i) the whole body, (ii) face/hands, prior to commencing non-PBS-subsidised therapy with this biological medicine
	AND
	Clinical criteria:
	The treatment must be the sole PBS-subsidised biological medicine for this PBS indication
	AND
	Clinical criteria:
	Patient must have achieved an adequate response to current non-PBS-subsidised therapy with this biological medicine, if they have received at least 16 weeks of therapy (or 24 weeks of therapy in the case of slow responder).
	Treatment criteria:
	Must be treated by a dermatologist; or
	Must be treated by a clinical immunologist
	Population criteria:
	Patient must be at least 12 years of age.
	Prescribing Instructions: State each of the 4 Eczema Area and Severity Index (EASI) symptom sub-score ratings for erythema, oedema/papulation, excoriation, lichenification that were present prior to having commenced non-PBS-subsidised therapy, in the authority application. The name/s of the medium to high potency topical corticosteroids trialled prior to commencing treatment with this biological medicine is/are to be documented in the patient's medical records. Alternatively, state the percentage of face/hand surface area affected by the condition (must be at least 30%) where EASI symptom sub-scores are not provided. This percentage surface area can also be stated in addition to the EASI symptom sub-scores. The EASI/percentage surface area and DLQI baseline measurements are to form the basis of determining if an adequate response to treatment has been achieved under the Continuing treatment restriction. In addition to stating them in this authority application, document them in the patient's medical records.
	Prescribing Instructions: A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under one of the following: (i) Continuing treatment, where there has been an adequate response to treatment (ii) Extended induction treatment (up to a further 8 weeks of therapy), where the patient has received 16 weeks of therapy, achieved a partial response and the prescriber considers that extended induction doses could result in achieving adequate response.
	Prescribing Instructions: This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

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

The sponsor had no comment.