5.26 Ustekinumab, Injection 45 mg in 0.5 mL, Injection 45 mg in 0.5 mL single use pre-filled pen, Injection 90 mg in 1 mL single use pre-filled pen, Steqeyma®, Celltrion

1 Purpose of Submission

1.1 The Category 4 submission requested PBS listing of the ustekinumab (Steqeyma) 45 mg subcutaneous (SC) vial and pre-filled pen (PFP), and 90 mg PFP presentations under the same circumstances as the PBS-listed ustekinumab (Steqeyma and Stelara®) products of the same strengths and for the same indications:

- Severe chronic plaque psoriasis (CPP)
- Severe psoriatic arthritis (PsA)
- Severe Crohn disease (CD)
- Complex refractory fistulising CD (fCD)
- Moderate to severe ulcerative colitis (MSUC).

1.2 The submission requested that biosimilar uptake drivers apply to the requested listings

1.3 The submission requested listing on a cost-minimisation basis to currently listed ustekinumab products at the same strengths.

2 Background

2.1 Table 1 shows the current PBS-listed forms of ustekinumab and the submission's requested dose forms.

2.2 Steqeyma was TGA registered on 11 September 2024 as a biosimilar to Stelara and with the same indications, including:

- adult patients (18 years or older) with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy
- moderate to severe plaque psoriasis in children and adolescent patients from 6 years of age who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies

- alone or in combination with methotrexate, the treatment of active psoriatic arthritis in adult patients (18 years and older) where response to previous non-biological disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate
- adult patients with moderately to severely active Crohn's disease who have had an inadequate response, lost response, or were intolerant to either conventional therapy or a TNFα antagonist or have medical contraindications to such therapies
- adult patients with moderately to severely active ulcerative colitis.

2.3 The Steqeyma 45 mg/0.5 mL PFP and 90 mg/1 mL PFP were TGA registered on 16 December 2025, and the Steqeyma 45 mg/0.5 mL vial was registered on 6 January 2026.

Table 1: PBS-listed forms of ustekinumab and requested Steqeyma dose forms

Indication	PBS listed dose forms	Recommended dosing (current PBS dose form units)	Requested dose forms (Steqeyma)
Severe CPP	Stelara: 45 mg vial, 90 mg PFS Steqeyma: 45 mg PFS, 90 mg PFS	Adult dosing: ≤100 kg: 45 mg >100 kg: 90 mg Paediatric dosing: <60 kg: 0.75 mg/kg (portion of 45 mg vial) ≥60 to ≤100 kg: 45 mg >100 kg: 90 mg SC injection at Weeks 0 and 4, then every 12 weeks	45 mg vial 45 mg PFP 90 mg PFP
Severe CD	Stelara: 45 mg vial, 90 mg PFS, 130 mg vial Steqeyma: 45 mg PFS, 90 mg PFS, 130 mg vial	Initiate with 260-520 mg IV infusion (2-4 x 130 mg vial) 90 mg SC injection at Week 8, then every 8 to 12 weeks	45 mg vial 45 mg PFP 90 mg PFP
Severe PsA	Stelara: 45 mg vial Steqeyma: 45 mg PFS	45 mg SC injection at Weeks 0 and 4, then every 12 weeks	45 mg vial 45 mg PFP
MUSC	Stelara: 90 mg PFS, 130 mg vial Steqeyma: 90 mg PFS, 130 mg vial	Initiate with 260-520 mg IV infusion (2-4 x 130 mg vial) 90 mg SC injection at Week 8, then every 8 to 12 weeks	90 mg PFP
Complex refractory fCD	Stelara: 90 mg PFS, 130 mg vial Steqeyma: 90 mg PFS, 130 mg vial	Initiate with 260-520 mg IV infusion (2-4 x 130 mg vial) 90 mg SC injection at Week 8, then every 8 to 12 weeks	90 mg PFP

Source: Main submission body p. 7,8
Abbreviations; CD = Crohn disease; CPP = chronic plaque psoriasis; fCD = fistulising Crohn disease; MUSC = moderate to severe ulcerative colitis; PFP = pre-filled pen; PsA = Severe psoriatic arthritis; SC = subcutaneous

Previous PBAC consideration

2.4 Steqeyma pre-filled syringes and injection vials were previously considered by the PBAC at its November 2024 meeting. The PBAC recommended Steqeyma 45 mg/0.5 mL pre-filled syringe (PFS), 90 mg/1 mL PFS and 130 mg/26 mL injection vial with schedule equivalence ('a' flag) for the same indications as Stelara. The PBAC

advised that biosimilar uptake drivers should apply to Steqeyma, that is, to have an Authority Required (STREAMLINED) restriction for the subsequent continuing treatment listings (Ustekinumab (Steqeyma) Public Summary Document [PSD], November 2024 PBAC meeting). Steqeyma was PBS listed on 1 August 2025.

2.5 At its March 2024 meeting, the PBAC recommended the listing of Stelara 45 mg and 90 mg PFS and PFP on the PBS under the same circumstances as the currently listed Stelara 45 mg vial for the treatment of severe PsA, severe CPP, severe CD, MSUC and fCD, but these presentations are not yet PBS listed. The PBAC recommended amendments to the prescribing instructions regarding the number of repeats and dosage to align with changes in the quantity required for adult patients following the proposed new listings. The PBAC made its recommendation based on, among other matters, its assessment that the cost-effectiveness of ustekinumab would be acceptable if it were cost-minimised to the least costly alternative (BDMARD) for each of the above-mentioned indications, based on previously advised equi-effective doses (*Ustekinumab (Stelara) PSD, March 2024 PBAC meeting*).

2.6 At its March 2024 meeting, the PBAC recommended listing the biosimilar Wezlana® in 45 mg/0.5 mL PFS, 45 mg/0.5 mL vial, 90 mg/1 mL PFS and 130 mg/26 mL vial forms. The PBAC recommended listing Wezlana under the same circumstances as Stelara, except for authority levels. The PBAC advised that biosimilar uptake drivers, including an Authority Required (STREAMLINED) listing for the subsequent continuing treatment phase should apply to the biosimilar brand. On 1 July 2026, Wezlana was PBS-listed as a biosimilar brand.

2.7 At its March 2025 meeting, the PBAC recommended the listing of another biosimilar, Epyztek® in the 45 mg/0.5 mL PFS, 90 mg/1 mL PFS and 130 mg/26 mL injection vial presentations under the same circumstances as Stelara. The PBAC recommended that biosimilar uptake drivers should apply to Epyztek. Epyztek has not yet been PBS listed.

2.8 At its March 2026 meeting, the PBAC recommended the listing of another biosimilar, Ardelya® in the 45 mg/0.5 mL PFS and 90 mg/1 mL PFS presentations for the treatment of adult patients with severe CPP or severe PsA under the same conditions as Stelara, but with authority levels consistent with Steqeyma to align with biosimilar uptake driver policy. Ardelya has not yet been PBS listed.

2.9 In December 2025, the PBAC recommended changes to the PBS restrictions for BDMARDs and targeted synthetic disease-modifying therapies, including ustekinumab, to support access for people with MUSC and severe CD who started advanced therapy during childhood, including through non-PBS pathways. Under the amended listings, prescribers will need to show that:

- treatment started before age 18 through a non-PBS pathway; and
- the patient met the paediatric PBS criteria for initial therapy at the time treatment started; and

- the patient has demonstrated or maintained an adequate clinical response.

2.10 At its March 2026 meeting, the PBAC recommended changes to the restrictions wording and prescribing instructions for multiple PBS listed medicines, including ustekinumab, for inflammatory bowel diseases (CD, MSUC and fCD). The changes include simplifying item codes; adjusting authority requirements; allowing greater flexibility around prior therapy requirements, dosing and assessment timeframes; and enabling patients who commenced treatment outside the PBS to transition to PBS subsidised therapy where eligibility can be demonstrated. Authority classifications will be simplified across all IBD listings, with initial therapy and originator continuing treatment classified as Authority Required (telephone/online) and biosimilar continuing treatment as Authority Required (STREAMLINED).

3 Requested listing

3.1 The submission requested listing of Steqeyma under the same circumstances as existing Stelara and Steqeyma listings of the same strength incorporating any amendments that were recommended by the PBAC at its March 2024 meeting (paragraph 6.1, ustekinumab (Stelara) PSD, March 2024 PBAC meeting).

3.2 The submission requested Authority Required (STREAMLINED) listings for both the first continuing and subsequent continuing treatment phases, including continuing treatment balance of supply listings. The current listings of Steqeyma are only Authority Required (STREAMLINED) for the subsequent continuing treatment phase.

3.3 The submission requested the following new/amended listings for Steqeyma, presented in an abridged version in the tables below:

- Amend ustekinumab listings for 45 mg/0.5 mL vial presentation, to add Steqeyma biosimilar with schedule equivalence (‘a’ flag) for the same indications as Stelara vial.
- Add new PBS listings for the Steqeyma 45 mg/0.5 mL vial presentation for the first continuing, subsequent continuing, and continuing balance of supply treatment phases, with Authority Required (STREAMLINED) restrictions.
- Add new PBS listings for the Steqeyma 45 mg/0.5 mL PFP and 90 mg/mL PFP for the same indications and under the same conditions as the currently listed PFS presentations of the same strength, with the following exceptions:
  - First continuing, subsequent continuing, and balance of supply listings to be Authority Required (STREAMLINED).
- Amend existing Steqeyma listings for the 45 mg/0.5 mL PFS and 90 mg/mL PFS to be Authority Required (STREAMLINED) for the first continuing, subsequent continuing, and continuing balance of supply listings.

3.4 While restriction changes for biosimilars for the treatment of CD, MSUC and fCD have yet to be finalised, the proposed restrictions for Steqeyma would be aligned with previous PBAC recommendations as follows:

- For the CD, MSUC and fCD indications, the first and subsequent continuing phases would be consolidated into a single continuing treatment phase at an Authority Required (STREAMLINED) restriction level and initial treatment would be via an Authority Required (telephone/online) restriction, to align with the PBAC's March 2026 consideration of IBD listings.
- For MSUC and CD indications, changes recommended by the PBAC in December 2025 to support access for people who started advanced therapy during childhood, including through non-PBS pathways would be incorporated.

3.5 The PBAC previously considered that the current biosimilar uptake arrangements should apply to the CPP and PsA indications, such that the first continuing treatment phase would remain Authority Required rather than Authority Required (STREAMLINED).

3.6 The submission requested for Steqeyma continuing treatment balance of supply listings to be Authority Required (STREAMLINED). The PBAC noted that there was no precedent for Authority Required (STREAMLINED) continuing treatment balance of supply listings for targeted therapies for these indications and considered that the authority level for these listings should remain consistent with existing arrangements.

3.7 The submission requested that Steqeyma 45 mg/0.5 mL vial and PFP, and 90 mg/1 mL PFP, be considered equivalent ('a' flagged) to the Stelara 45 mg/0.5 mL vial and 90 mg/1 mL PFP, and the Steqeyma 45 mg/0.5 mL PFS and 90 mg/0.5 mL PFS of the same dose and form.

3.8 As the submission requests the same restrictions as the reference brand, the full restrictions have not been reproduced here. Secretariat suggested amendments, that also reflect the PBAC's March 2026 and December 2025 recommendations, are in italics and deletions are in strikethrough.

3.9 Add new PBS item codes or new brand to existing item codes, where relevant:

Severe chronic plaque psoriasis

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
Adult Initial 1, 2, 3 (face/hand/foot, whole body), Balance of supply – Initial 1, 2, 3 (whole body, face/hand/foot) – Authority Required					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial	9304Q	1	1	2	Stelara[a] *Steqeyma*[a]
ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe	14892T	1	1	2	Steqeyma
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pen device	NEW	1	1	2	Steqeyma
ustekinumab 90 mg/mL injection, 1 mL syringe	14935C	1	1	2	Steqeyma
ustekinumab 90 mg/mL injection, 1 mL pen device	NEW	1	1	2	Steqeyma
Adult First continuing (whole body, face/hand/foot), Subsequent continuing (whole body, face/hand/foot), Balance of supply – Continuing (whole body, face/hand/foot) – Authority Required					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial	9305R	1	1	1	Stelara[a] *Steqeyma*[a]
Adult First continuing (whole body or face/hand/foot), Balance of supply – Continuing treatment (whole body, face/hand/foot) – Authority Required					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe	14899E	1	1	1	Steqeyma
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pen device	NEW	1	1	1	Steqeyma
ustekinumab 90 mg/mL injection, 1 mL syringe	14893W	1	1	1	Steqeyma
ustekinumab 90 mg/mL injection, 1 mL pen device	NEW	1	1	1	Steqeyma
Adult Subsequent continuing (whole body, face/hand/foot) – STREAMLINED					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial	NEW	1	1	1	Steqeyma
ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe	14944M	1	1	1	Steqeyma
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pen device	NEW	1	1	1	Steqeyma
ustekinumab 90 mg/mL injection, 1 mL syringe	14917D	1	1	1	Steqeyma
ustekinumab 90 mg/mL injection, 1 mL pen device	NEW	1	1	1	Steqeyma
Paediatric Initial 1, 2, 3 (face/hand/foot, whole body), Balance of supply – Initial 1, 2, 3 (whole body or face/hand/foot) – Authority Required					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial	12669T	1	1	2	Stelara[a] *Steqeyma*[a]
ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe	14879D	1	1	2	Steqeyma
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pen device	NEW	1	1	2	Steqeyma
ustekinumab 90 mg/mL injection, 1 mL syringe	14897C	1	1	2	Steqeyma
ustekinumab 90 mg/mL injection, 1 mL pen device	NEW	1	1	2	Steqeyma

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
Paediatric First continuing (whole body, face/hand/foot) – treatment covering week 28 and onwards, Subsequent continuing (whole body, face/hand/foot) – Authority required					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial	12664M	1	1	1	Stelara[a] *Steqeyma*[a]
Paediatric First continuing (whole body, face/hand/foot) – treatment covering week 28 and onwards – Authority required					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe	14891R	1	1	1	Steqeyma
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pen device	NEW	1	1	1	Steqeyma
ustekinumab 90 mg/mL injection, 1 mL syringe	14943L	1	1	1	Steqeyma
ustekinumab 90 mg/mL injection, 1 mL pen device	NEW	1	1	1	Steqeyma
Paediatric Balance of supply (whole body, face/hand/foot) – First continuing and Subsequent continuing – Authority Required					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial	12662K	1	1	0	Stelara[a] *Steqeyma*[a]
ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe	14890Q	1	1	0	Steqeyma
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pen device	NEW	1	1	0	Steqeyma
Paediatric Subsequent continuing (whole body, face/hand/foot) – STREAMLINED					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial	NEW	1	1	1	Steqeyma
ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe	14933Y	1	1	1	Steqeyma
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pen device	NEW	1	1	1	Steqeyma
ustekinumab 90 mg/mL injection, 1 mL syringe	14878C	1	1	1	Steqeyma
ustekinumab 90 mg/mL injection, 1 mL pen device	NEW	1	1	1	Steqeyma

a= 'a' flagging

Severe psoriatic arthritis

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
Initial 1, 2, 3, Balance of supply – Initial 1, 2, 3 – Authority Required					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial	10774C	1	1	2	Stelara[a] *Steqeyma*[a]
ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe	14916C	1	1	2	Steqeyma
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pen device	NEW	1	1	2	Steqeyma
First continuing, Subsequent continuing, Balance of supply – First continuing and Subsequent continuing – Authority Required					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial	10767Q	1	1	1	Stelara[a] *Steqeyma*[a]
First continuing, Balance of supply – First continuing and Subsequent continuing – Authority Required					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe	14908P	1	1	1	Steqeyma
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pen device	NEW	1	1	1	Steqeyma
Subsequent continuing – STREAMLINED					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial	NEW	1	1	1	Steqeyma
ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe	14877B	1	1	1	Steqeyma
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pen device	NEW	1	1	1	Steqeyma

a= 'a' flagging

Severe Crohn disease

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
Adult Initial 1, 2, 3, ~~First continuing, Subsequent continuing~~ *Continuing, Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient,* Balance of supply – Authority Required ~~(Written)~~ *(Telephone/Online PBS Authorities' System)*					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial	11178H	2	2	0	Stelara[a] *Steqeyma*[a]
Adult Continuing (biosimilar brands only) – STREAMLINED					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial	NEW	2	2	2	Steqeyma
Adult Initial 1, 2, 3, ~~First continuing~~ *Continuing, Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient,* Balance of supply – Authority Required ~~(Written)~~ *(Telephone/Online PBS Authorities' System)*					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe	14898D	2	2	0	Steqeyma
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pen device	NEW	2	2	0	Steqeyma
ustekinumab 90 mg/mL injection, 1 mL syringe	14934B	1	1	0	Steqeyma
ustekinumab 90 mg/mL injection, 1 mL pen device	NEW	1	1	0	Steqeyma
Adult ~~Subsequent~~ Continuing *(biosimilar brands only)* – STREAMLINED					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe	14909Q	2	2	2	Steqeyma
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pen device	NEW	2	2	2	Steqeyma
ustekinumab 90 mg/mL injection, 1 mL syringe	14926N	1	1	2	Steqeyma
ustekinumab 90 mg/mL injection, 1 mL pen device	NEW	1	1	2	Steqeyma

a= 'a' flagging

Complex refractory fistulising Crohn disease

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
Initial 1, 2, Balance of supply – Initial 1, 2 – Authority Required ~~(Written)~~ *(Telephone/Online PBS Authorities' System)*					
ustekinumab 90 mg/mL injection, 1 mL syringe	13805N	1	1	0	Stelara[a] Steqeyma[a]
ustekinumab 90 mg/mL injection, 1 mL pen device	NEW	1	1	0	Steqeyma
~~First continuing, Subsequent continuing~~ *Continuing* – Authority required ~~(Written)~~ *(Telephone/Online PBS Authorities' System)*					
ustekinumab 90 mg/mL injection, 1 mL syringe	13789R	1	1	1	Stelara[a] Steqeyma[a]
ustekinumab 90 mg/mL injection, 1 mL pen device	NEW	1	1	1	Steqeyma
~~Subsequent continuing~~ *Continuing (biosimilar brands only)* – STREAMLINED					
ustekinumab 90 mg/mL injection, 1 mL syringe	14907N	1	1	2	Steqeyma
ustekinumab 90 mg/mL injection, 1 mL pen device	NEW	1	1	2	Steqeyma

a= 'a' flagging

Moderate to severe ulcerative colitis

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
Initial 1, 2, 3 – Authority Required ~~(Written)~~ *(Telephone/Online PBS Authorities' System)*					
ustekinumab 90 mg/mL injection, 1 mL syringe	13273N	1	1	0	Stelara[a] Steqeyma[a]
ustekinumab 90 mg/mL injection, 1 mL pen device	NEW	1	1	0	Steqeyma
~~First continuing, Subsequent continuing, Balance of supply – First continuing and Subsequent continuing~~ *Continuing, Balance of supply – Continuing, Transitioning from non-PBS-subsidised therapy that was commenced as a paediatric patient* – Authority Required (Telephone/Online PBS Authorities' System)					
ustekinumab 90 mg/mL injection, 1 mL syringe	13261Y	1	1	1	Stelara[a] Steqeyma[a]
ustekinumab 90 mg/mL injection, 1 mL pen device	NEW	1	1	1	Steqeyma
~~Subsequent continuing~~ *Continuing (biosimilar brands only)* – Streamlined					
ustekinumab 90 mg/mL injection, 1 mL syringe	14918E	1	1	2	Steqeyma
ustekinumab 90 mg/mL injection, 1 mL pen device	NEW	1	1	2	Steqeyma

a= 'a' flagging

4 Comparator

4.1 The submission proposed ustekinumab at the same dose in any form as the comparator for the new listings, specifically:

- Ustekinumab 45 mg/0.5 mL (available on the PBS as Steqeyma 45 mg/0.5 mL PFS and Stelara 45 mg/0.5 mL vial) as the comparator for the Steqeyma 45 mg/0.5 mL vial and PFP. The PBAC noted that the Steqeyma 45 mg/0.5 mL vial would be considered a new biosimilar brand of the currently listed Stelara 45 mg/0.5 mL vial.
- Ustekinumab 90 mg/1 mL (available on the PBS as 90 mg/1 mL PFS in Stelara or Steqeyma brands) as the comparator for the Steqeyma 90 mg/1 mL PFP.

4.2 As per the Product Information, the TGA has confirmed that Steqeyma is a biosimilar medicine to Stelara (ustekinumab). The evidence for comparability supports the use of Steqeyma for the listed indications.

5 Consideration of the evidence

Sponsor hearing

5.1 There was no hearing for this item.

Consumer inputs

5.2 Six consumer inputs were received, including five from individuals living with Crohn disease and one consumer organisation submission from Crohn's & Colitis Australia. Three individuals had experience using ustekinumab and reported improvements in symptom control, wellbeing and daily functioning, including greater ability to work, eat and participate in everyday activities. Consumers described benefits such as reduced inflammation, improved quality of life and the convenience of home administration.

5.3 Some concerns were raised about treatment access, including medicine costs, supply delays, storage and travel requirements associated with refrigerated injections, and the challenges of infrequent dosing schedules.

5.4 One consumer reported worsening disease markers and loss of remission following a switch from the originator product to a biosimilar. Safety concerns were generally limited, with reports including transient fatigue following injection.

5.5 Some consumers considered that a benefit of ustekinumab treatment was the reduced risk of side effects compared to alternative immunosuppressive therapies.

5.6 Two consumers seeking access to ustekinumab identified a need for additional treatment options for Crohn disease, with one noting concerns regarding current treatment options while planning pregnancy and considering ustekinumab as a potentially better tolerated alternative.

Clinical evidence

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

Clinical trials

5.8 The sponsor presented the following clinical trials in Table 2 to support the claim of biosimilarity between Steqeyma and Stelara in its November 2024 submission (*Ustekinumab (Steqeyma) PSD, November 2024 PBAC Meeting*). These trials formed part of the TGA submission for Steqeyma.

Table 2: Studies presented in the submission.

Trial ID	Publication title	Publication citation
Study CT-P43 3.1 NCT04673786	Anonymous. "CT-P43 3.1: A Randomized, Active-Controlled, Double-Blind, Phase 3 Study to Compare the Efficacy and Safety of CT-P43 to Stelara in Patients With Moderate to Severe Plaque Psoriasis"	*ClinicalTrials* 2020; 13.
	Papp KA, *et al*. Efficacy and Safety of Candidate Biosimilar CT-P43 Versus Originator Ustekinumab in Moderate to Severe Plaque Psoriasis: 28-Week Results of a Randomised, Active-Controlled, Double-Blind, Phase III Study.	*BioDrugs* 2023; 38(1): 121-131.
	Papp, *et al.* "Efficacy and Safety of CT-P43, a Candidate Ustekinumab Biosimilar, in Moderate-to-Severe Plaque Psoriasis: 52-Week Results From a Randomised, Active-Controlled, Double-Blind, Phase III Study."	Dermatologic Therapy 2026; 1 (no pagination).

Source: Table 2-3, Main submission body.

5.9 The PBAC noted that no new clinical trial data or other comparative data were presented in this submission.

Economic analysis

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

5.11 The submission presented a cost-minimisation analysis of Steqeyma 45 mg and 90 mg PFP and 45 mg vial compared with the currently listed Steqeyma and Stelara products of the same strengths in PFS and vial presentations. The submission stated that Steqeyma will directly substitute on a 1:1 basis for the currently listed ustekinumab products.

5.12 The submission proposed an ex-manufacturer price of $716.69 for the 45 mg forms, and $892.04 for the 90 mg PFP, consistent with the prices of the PBS-listed 45 mg and 90 mg forms as at 1 June 2026.

Estimated PBS usage and financial implications

5.13 The submission presented a market-share approach. As the proposed listing is expected only to displace existing use of the ustekinumab PFS and vials, there is expected to be nil financial impact to the PBS/RPBS with the proposed listing.

5.14 The PBAC noted that the listing of biosimilar brands does not change overall utilisation of the drug.

5.15 The financial impact to Services Australia will be determined by that agency as part of the post PBAC process.

6 PBAC Outcome

6.1 The PBAC recommended the PBS listing of ustekinumab (Steqeyma) 45 mg/0.5 mL vial, 45 mg/0.5 mL single use PFP and 90 mg/1 mL single use PFP for the treatment of severe chronic plaque psoriasis, severe psoriatic arthritis, severe Crohn disease, complex refractory fistulising Crohn disease and moderate to severe ulcerative colitis, under the same circumstances as the currently listed ustekinumab products of the same strengths, subject to the authority levels and administrative arrangements outlined below.

6.2 The PBAC recommended the listing of Steqeyma on a cost-minimisation basis compared with the currently listed ustekinumab products of the same strengths. The PBAC noted that Steqeyma is registered by the TGA as a biosimilar to Stelara and considered that the requested listings were consistent with previous PBAC recommendations for ustekinumab biosimilars. The PBAC also considered that the application of biosimilar uptake drivers to Steqeyma would be clinically appropriate and would not impact cost-effectiveness.

6.3 The PBAC considered that, for severe Crohn disease, complex refractory fistulising Crohn disease and moderate to severe ulcerative colitis, the restrictions for Steqeyma should align with the PBAC's March 2026 recommendations for inflammatory bowel disease listings. The PBAC considered that the authority levels for initial treatment should be listed as Authority Required (telephone/online) and that the first and subsequent continuing phases would be consolidated into a single continuing treatment phase at an Authority Required (Streamlined) level.

6.4 The PBAC also considered that for severe Crohn disease and moderate to severe ulcerative colitis indications, changes recommended by the PBAC in December 2025 to support access for people who started advanced therapy during childhood, including through non-PBS pathways should be incorporated.

6.5 The PBAC considered that, for severe chronic plaque psoriasis and severe psoriatic arthritis, the current biosimilar uptake arrangements should continue to apply. The PBAC considered that the first continuing treatment phase and balance of supply listings should be Authority Required (telephone/online), with Authority Required (STREAMLINED) restrictions applying only to the subsequent continuing treatment phase.

6.6 The PBAC noted that the Stelara 90 mg/1 mL PFP is not currently PBS listed and therefore considered that 'a' flagging between the Stelara and Steqeyma PFP presentations at this strength could not occur at this time. The PBAC considered it appropriate for the ustekinumab PFS and PFP presentations of the same strength to be treated as equivalent for the purposes of substitution for 'a' flagging and recommended the addition of administrative advice notes to the following effect:

- *'Pharmaceutical benefits that have the form ustekinumab 45 mg/0.5 mL pen device and pharmaceutical benefits that have the form ustekinumab 45 mg/0.5 mL injection syringe are equivalent for the purposes of substitution.'*
- *'Pharmaceutical benefits that have the form ustekinumab 90 mg/1 mL pen device and pharmaceutical benefits that have the form ustekinumab 90 mg/1 mL injection syringe are equivalent for the purposes of substitution.'*

6.7 The PBAC advised, under section 101(4AACD) of the *National Health Act 1953*, that the Steqeyma 45 mg/0.5 mL vial and the Stelara 45 mg/0.5 mL vial should be treated as equivalent for the purposes of substitution. The PBAC advised that vial and PFP presentations should not be treated as equivalent for the purposes of substitution.

6.8 The PBAC also advised that 'a' flagging between the vial and PFS was not recommended by the PBAC previously (paragraph 5.6, ustekinumab (Epyztek) PSD, March 2025 PBAC meeting) and thus should also not occur between the vial and the PFP.

6.9 The PBAC noted that the standard 'Biosimilar prescribing policy' administrative note encouraging the use of biosimilar brands for treatment naïve patients would be applied to any new and amended Initial 1, 2, 3 and Initial – balance of supply listings:

"Prescribing of a biosimilar brand where available is encouraged for treatment naïve patients.

Encouraging biosimilar prescribing for treatment naïve patients is Government policy. A viable biosimilar market is expected to result in reduced costs for targeted therapies, allowing the Government to reinvest in new treatments. Further information can be found on the Biosimilar Medicines webpage (www.health.gov.au/health-topics/medicines)"

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

Outcome:
Recommended

Please note that the web outcome included below is provided for your information and may be subject to minor editorial refinement prior to publication. Any such changes are not expected to materially affect the meaning of the outcome.

7 Recommended listing

7.1 The restrictions are complex due to the number of PBS item codes and indications requested for listing. As the submission requested the same restrictions as the existing PBS-listed ustekinumab products, the full restrictions have not been reproduced.

7.2 Add Steqeyma biosimilar brand with schedule equivalence ('a' flag) for the same indications as PBS-listed Stelara for the 45 mg/0.5 mL vial formulation.

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
USTEKINUMAB					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial	Multiple (existing)	-	-	-	[a]Stelara [a]Wezlana [a]*Steqeyma*

a= 'a' flagging

7.3 Add new PBS item codes for Steqeyma 45 mg/0.5 mL and 90 mg/1 mL pre-filled pen formulations for the same indications as Stelara, along with administrative advice notes to allow cross item code substitution.

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
USTEKINUMAB					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pen device	NEW (Multiple)	-	-	-	Steqeyma
ustekinumab 90 mg/mL injection, 1 mL pen device					
	Administrative advice: Pharmaceutical benefits that have the form ustekinumab 45 mg/0.5 mL pen device and pharmaceutical benefits that have the form ustekinumab 45 mg/0.5 mL injection syringe are equivalent for the purposes of substitution.				
	Administrative advice: Pharmaceutical benefits that have the form ustekinumab 90 mg/0.5 mL pen device and pharmaceutical benefits that have the form ustekinumab 90 mg/0.5 mL injection syringe are equivalent for the purposes of substitution.				

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

8 Context for Decision

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

9 Sponsor's Comment

The sponsor had no comment.