5.27 USTEKINUMAB,
Injection 45 mg in 0.5 mL
Injection 45 mg in 0.5 mL single use pre-filled syringe
Injection 90 mg in 1 mL single use pre-filled syringe
Solution for I.V. infusion 130 mg in 26 mL,
Yesintek®,
Generic Health Pty Ltd

1 Purpose of Submission

1.1 The Category 3 submission requested to list under a new biosimilar brand of ustekinumab,

- injection 45 mg in 0.5 mL
- injection 45 mg in 0.5 mL single use pre-filled syringe (PFS)
- injection 90 mg in 1 mL single use PFS
- solution for I.V. infusion 130 mg in 26 mL

Yesintek® under the same circumstances as the PBS-listed reference biologic Stelara® for the treatment of:

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

This was under the General Schedule and Section 100 (Highly Specialised Drugs) funding programs.

1.2 Listing was requested on a cost-minimisation basis to Stelara.

2 Background

2.1 The requested ustekinumab biosimilar, herein referred to Yesintek throughout the document, was TGA registered on 19 March 2026 for the treatment of:

- **Moderate to severe plaque psoriasis**
  - in adult patients (18 years or older) who are candidates for phototherapy or systemic therapy

  - in children and adolescent patients from 6 years of age who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies.
- signs and symptoms of **active psoriatic arthritis** in adult patients (18 years and older) where response to previous non-biological DMARD therapy has been inadequate, alone or in combination with methotrexate
- 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**.

Yesintek was determined to be biosimilar to the reference brand, herein referred to as Stelara throughout the document.

2.2 The PBAC previously recommended four other biosimilar brands at the following meetings:

- Steqeyma® at the November 2024 PBAC meeting
- Wezlana® at the March 2024 PBAC meeting
- Epyztek® at the March 2025 PBAC meeting
- Ardelya® at the March 2026 PBAC meeting

On 1 August 2025, Steqeyma was listed on the PBS as the first biosimilar brand for ustekinumab for the same indications as Stelara. On 1 July 2026, Wezlana was similarly listed as a biosimilar brand. As of July 2026, Epyztek and Ardelya have not yet been PBS listed.

2.3 The sponsor requests to list Yesintek on the PBS under the same strengths, dosage forms and indications as the reference brand Stelara, and the same authority arrangements as those currently applying to biosimilar Steqeyma. See Section 3: Requested listing for further details.

2.4 Yesintek has not previously been considered by the PBAC.

2.5 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.

2.6 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
- 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 Yesintek under the same circumstances as the PBS-listed reference biologic **Stelara** and biosimilar **Steqeyma**.

Stelara is listed on the PBS for the following strengths and forms:

- injection 45 mg in 0.5 mL
- injection 90 mg in 1 mL single use pre-filled syringe
- solution for I.V. infusion 130 mg in 26 mL.

Steqeyma is listed on the PBS for the following strengths and forms:

- injection 45 mg in 0.5 mL single use pre-filled syringe
- injection 90 mg in 1 mL single use pre-filled syringe
- solution for I.V. infusion 130 mg in 26 mL.

3.2 At its July 2026 meeting, the PBAC will be considering whether to add new forms of the biosimilar brand Steqeyma to the PBS:

- injection 45 mg in 0.5 mL
- injection 45 mL in 0.5 mL single use pre-filled pen
- injection 90 mL in 1 mL single use pre-filled pen.

3.3 The submission also requested that the proposed restrictions for Yesintek should align with the biosimilar medicines (previously recommended by PBAC), as per the biosimilar uptake driver policy.

3.4 As the submission requested the same restrictions as the reference brands, the full restrictions have not been reproduced here, however an example has been included below (for 'Severe Crohn disease', treatment phases: Initial 1, 2 and 3):

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
USTEKINUMAB					
ustekinumab 130 mg/26 mL injection, 26 mL vial	11164N	4	4	0	[a]Stelara [a]Steqeyma [a]Wezlana [a]*Yesintek*

3.5 The submission requested that Yesintek be considered equivalent ('a'-flagged) to Stelara and Steqeyma for the purpose of substitution.

4 Consideration of the evidence

Consumer inputs

4.1 The PBAC noted and welcomed input from individuals (4) and consumer groups (1) via the Office of Health Technology Assessment Consultation Hub.

4.2 Input from consumers wanting to access the medicine described ongoing symptoms and significant disease burden despite current treatment. Contributors highlighted impacts on daily life and wellbeing, including prior surgery, persistent inflammation, fatigue, pain, bloating and constipation. The input suggested access to newer and more targeted treatment options may improve symptom control, quality of life and longer terms outcomes, particularly for those who had not responded adequately to existing medicines or had experienced complications. Input from consumers currently using ustekinumab noted that pre-filled syringes were easier to administer and were more manageable. One consumer noted their experience of poorer treatment outcomes when switching from Stelara to the biosimilar Steqeyma.

4.3 The PBAC noted that while some of the consumer inputs received were not directly related to the submission request, they reflected lived experiences with ustekinumab that the individuals considered relevant to the broader context of its use.

4.4 The PBAC advised that input from consumers is most useful when it relates directly to the indication being considered but acknowledged the value of broader perspectives in understanding community experiences with medicines.

4.5 The PBAC advised that consumers seeking to contribute to future consultations may benefit from resources that explain the PBAC process and how to tailor input effectively, such as those available through the Office of Health Technology Assessment Consultation Hub (Office of Health Technology - Citizen Space).

Clinical evidence

4.6 As a Category 3 submission, the clinical evidence was not independently evaluated.

4.7 The TGA has confirmed that in equal doses Yesintek is the same as Stelara (TGA Delegate's Overview).

4.8 According to the TGA Delegate's Overview, no significant differences regarding safety were identified between Yesintek and Stelara. However, a higher incidence of mild to moderate treatment-emergent adverse events was noted with Yesintek, primarily related to infections.

4.9 The PBAC considered that the claim of bio-similarity between Yesintek and Stelara was adequately supported by the data.

Estimated PBS usage and financial implications

4.10 As a Category 3 submission, the economic evaluation was not independently evaluated.

4.11 Listing of biosimilar brands does not change overall utilisation of the drug. The sponsor provided the following financial and economic information.

4.12 In estimating the forecasted volume of Yesintek through the market share approach, the sponsor used estimates for items with complete and representative PBS data only. This meant the exclusion of utilisation data only available for 2025. Utilisation data for syringe presentation was also limited to only a partial year due to Steqeyma only being listed on 1 August 2025.

4.13 The sponsor described the market as in the early stages of establishment, given it comprises one long-established reference brand and a biosimilar brand that was only listed in the most recent year. As such, overall market familiarity with biosimilar ustekinumab is developing and not yet mature.

4.14 The sponsor assumed the uptake of Yesintek would be gradual, reflecting:

- existing prescriber familiarity with the reference product
- early but increasing acceptance of ustekinumab biosimilars following recent PBS listings
- conservative expectations for switching behaviour in the initial years post-listing.

4.15 The submission estimated no additional financial impact on the PBS.

5 PBAC Outcome

5.1 The PBAC recommended the listing of ustekinumab biosimilar brand Yesintek under the same circumstances as the PBS-listed reference biologic Stelara, under General Schedule and Section 100 Highly Specialised Drugs Program listings.

5.2 The PBAC noted that the TGA has confirmed bio-similarity between Yesintek and reference product Stelara.

5.3 The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of Yesintek would be acceptable if it were cost minimised to Stelara at the effective price.

5.4 The PBAC advised the equi-effective doses to be 1 mg Yesintek = 1 mg Stelara – in other words, the following:

- Yesintek injection 45 mg in 0.5 mL = Stelara injection 45 mg in 0.5 mL
- Yesintek injection 45 mg in 0.5 mL single use PFS = Stelara injection 45 mg in 0.5 mL single use PFS
- Yesintek injection 90 mg in 1 mL single use PFS = Stelara injection 90 mg in 1 mL single use PFS
- Yesintek solution for I.V. infusion 130 mg in 26 mL = Stelara solution for I.V. infusion 130 mg in 26 mL.

5.5 The PBAC advised that the PBAC's December 2025 recommendation for BDMARDs would apply for the moderate to severe ulcerative colitis and severe Crohn's disease indications of Yesintek. This change would apply new restrictions that support access for people who started advanced therapy during childhood.

5.6 Additionally, the PBAC advised that the PBAC's March 2026 recommendation for IBD indications would apply for Yesintek. This change would consolidate restrictions for initial and continuing treatment for Severe Crohn's disease, moderate to severe ulcerative colitis and complex refractory fistulising Crohn's disease.

5.7 The PBAC noted the current biosimilar uptake driver policy, that is, an Authority Required (STREAMLINED) requirement for the subsequent continuing treatment listings and the inclusion of an administrative note encouraging use of the biosimilar brand for treatment naïve patients, should continue to apply for the severe chronic plaque psoriasis and severe psoriatic arthritis indications for Yesintek. The PBAC considered that the application of biosimilar uptake drivers to Yesintek would be clinically appropriate and would not impact cost-effectiveness.

5.8 The PBAC advised that under Section 101(4AACD) of the National Health Act 1953, Yesintek and PBS listed ustekinumab brands of the equivalent strengths and forms, should be treated as equivalent to each other (i.e., 'a'-flagged in the Schedule).

5.9 The PBAC considered that the listing of Yesintek would not result in a net cost to the PBS as it would likely substitute for Stelara and not increase the overall market utilisation.

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

5.11 The PBAC advised that Yesintek is suitable for prescribing by medical practitioners only.

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

Outcome:
Recommended

6 Recommended listing

6.1 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 reference biologic, Stelara, the full restrictions have not been reproduced.

6.2 Add Yesintek biosimilar brand with schedule equivalence ('a'-flag) for the same indications as Stelara and apply the biosimilar uptake policy to Yesintek.

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
USTEKINUMAB					
ustekinumab 130 mg/26 mL injection, 26 mL vial	Multiple	-	-	-	[a]Stelara [a]Steqeyma [a]Wezlana [a]Yesintek
ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial					
ustekinumab 90 mg/mL injection, 1 mL syringe					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe					

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

7 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.

8 Sponsor's Comment

The sponsor had no comment.