5.19 USTEKINUMAB, Injection 45 mg in 0.5 mL single use pre-filled syringe, Injection 90 mg in 1 mL single use pre-filled syringe, Ardelya®, Sandoz Pty Ltd

1 Purpose of Submission

1.1 The Category 3 submission requested General Schedule Authority Required listings of a new ustekinumab biosimilar (Ardelya®) in 45 mg and 90 mg pre-filled syringe (PFS) forms for the treatment of adult patients with severe chronic plaque psoriasis and severe psoriatic arthritis.

1.2 Listing was requested on a cost-minimisation basis and under the same conditions as its reference biologic (Stelara®).

2 Background

2.1 At the time of submission (November 2025), the product was sponsored by Cipla Australia Pty Ltd and marketed under the brand name Uteknix®. However, by the time of the March 2026 PBAC meeting, sponsorship of the product is expected to have transferred to Sandoz, and the product will be marketed as Ardelya.

Registration status

2.2 Ardelya was TGA registered on 11 February 2025 and was determined to be a biosimilar medicine to the reference brand (Stelara).

2.3 Ardelya is not TGA approved for Crohn disease and ulcerative colitis, or for plaque psoriasis in children and adolescents; these indications require vial presentations that were still under development at the time of the submission.

3 Requested listing

3.1 The submission requested that the essential elements of the requested (PFS) listings for Ardelya mirror those of Stelara for the severe chronic plaque psoriasis and severe psoriatic arthritis (adult) indications only.

3.2 The Secretariat noted that Stelara has both a 45 mg vial form and a 45 mg PFS form, but the latter is not yet PBS-listed. Stelara does have a 90 mg PFS form but not for severe chronic plaque psoriasis or severe psoriatic arthritis. Steqeyma (the first ustekinumab biosimilar on the PBS) has both a 45 mg and 90 mg PFS form.

3.3 The submission requested that administrative advice be added reflecting the biosimilar uptake policy (i.e. encouraging uptake of biosimilar prescribing for

treatment-naïve patients) to the initial listings. The Secretariat noted that this advice already exists in the listings.

3.4 As the submission requested the same restrictions as the reference brand, the full restrictions have not been reproduced here.

3.5 Add brand to existing items:

Severe chronic plaque psoriasis (adult)

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
USTEKINUMAB **Initial 1, 2, 3 (face, hand, foot), Initial 1, 2, 3 (whole body), balance of supply**					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pre-filled syringe	14892T	1	1	2	Steqeyma[a] *Ardelya*[a]
ustekinumab 90 mg/mL injection, 1 mL pre-filled syringe	14935C	1	1	2	Steqeyma[a] *Ardelya*[a]
USTEKINUMAB **First continuing treatment whole body or face/hand/foot, balance of supply**					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pre-filled syringe	14899E	1	1	1	Steqeyma[a] *Ardelya*[a]
ustekinumab 90 mg/mL injection, 1 mL pre-filled syringe	14893W	1	1	1	Steqeyma[a] *Ardelya*[a]
USTEKINUMAB **Subsequent continuing treatment (whole body or face/hand/foot)**					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pre-filled syringe	14944M	1	1	1	Steqeyma[a] *Ardelya*[a]
ustekinumab 90 mg/mL injection, 1 mL pre-filled syringe	14917D	1	1	1	Steqeyma[a] *Ardelya*[a]

Severe psoriatic arthritis

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
USTEKINUMAB **Initial 1, 2, 3, balance of supply**					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pre-filled syringe	14916C	1	1	2	Steqeyma[a] *Ardelya*[a]
USTEKINUMAB **First continuing, balance of supply, subsequent continuing**					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pre-filled syringe	14908P	1	1	1	Steqeyma[a] *Ardelya*[a]
USTEKINUMAB **Subsequent continuing**					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pre-filled syringe	14877B	1	1	1	Steqeyma[a] *Ardelya*[a]

3.6 The submission requested that Ardelya be considered equivalent ('a' flagged) to Stelara for the purpose of substitution. The Secretariat noted that 'a' flagging can only

occur between equivalent injection devices that contain the same injectable mg dose per volume. In this case, Ardelya cannot be 'a' flagged to Stelara.

3.7 Ardelya will have the same drug, form and manner of administration as the existing ustekinumab brands and, as such, will be required to have the same approved ex-manufacturer price (AEMP) as the existing ustekinumab brands as per Section 85C of the National Health Act 1953.

4 Consideration of the evidence

Sponsor hearing

4.1 There was no hearing for this item.

Consumer inputs

4.2 The PBAC noted that no consumer inputs were received for this item.

Clinical evidence

4.3 The TGA evaluation concluded that Ardelya demonstrated biosimilarity to the reference product Stelara and recommended approval for the proposed indications.

4.4 The submission stated that the equi-effective doses are: 1 mg Ardelya = 1 mg Stelara.

4.5 As a Category 3 submission, the clinical evidence has not been independently evaluated.

Estimated PBS usage and financial implications

4.6 Listing of biosimilar brands does not change overall utilisation of the drug.

4.7 Ardelya is expected to substitute for Stelara and Steqeyma, as such, there is expected to be nil financial impact to the PBS/RPBS with the proposed listing.

5 PBAC Outcome

5.1 The PBAC recommended the General Schedule Authority Required listing of a new ustekinumab biosimilar (Ardelya®) in 45 mg and 90 mg pre-filled syringe (PFS) forms for the treatment of adult patients with severe chronic plaque psoriasis and severe psoriatic arthritis on a cost-minimisation basis and under the same conditions as its reference biologic (Stelara®).

5.2 The PBAC advised the equi-effective doses to be 1 mg Ardelya = 1 mg Stelara.

5.3 The PBAC noted that the TGA has confirmed that Ardelya is a biosimilar medicine to Stelara.

5.4 The PBAC noted that in their pre-PBAC response, the sponsor confirmed that the authority levels for Ardelya should be consistent with those for Steqeyma (the first ustekinumab biosimilar to be listed on the PBS), which aligns with the biosimilar uptake driver policy. The PBAC also noted that the submission requested the addition

of administrative advice reflecting the biosimilar uptake driver that encourages biosimilar prescribing for treatment-naïve patients (which already exists in the listings). The PBAC considered that the application of both biosimilar uptake drivers to Ardelya would be clinically appropriate.

5.5 The PBAC advised that, under Section 101(4AACD) of the *National Health Act 1953*, Ardelya and Steqeyma should be considered equivalent for the purpose of substitution at the pharmacy level (i.e., 'a' flagged in the Schedule of Pharmaceutical Benefits) as Ardelya and Stelara do not currently share equivalent injection devices that contain the same injectable mg dose per volume.

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

5.7 The PBAC noted its recommendation was on a cost-minimisation basis and advised that, because Ardelya is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity over Stelara, and is not expected to address a high and urgent unmet clinical need given the presence of alternative therapies, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met.

5.8 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 As the submission requested the same restrictions as the existing brands, the full restrictions have not been reproduced.

6.2 Add Ardelya biosimilar listing with schedule equivalence ('a' flag) to Steqeyma.

6.3 Amend existing listing as follows:

- Add the Ardelya brand – with the Authority type for each treatment phase to be consistent with Steqeyma.

Severe chronic plaque psoriasis (adult)

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ustekinumab 90 mg/mL injection, 1 mL syringe	14935C	1	1	2	Steqeyma[a] *Ardelya*[a]
USTEKINUMAB **First continuing treatment whole body or face/hand/foot, balance of supply**					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe	14899E	1	1	1	Steqeyma[a] *Ardelya*[a]
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USTEKINUMAB **Subsequent continuing treatment (whole body or face/hand/foot)**					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe	14944M	1	1	1	Steqeyma[a] *Ardelya*[a]
ustekinumab 90 mg/mL injection, 1 mL syringe	14917D	1	1	1	Steqeyma[a] *Ardelya*[a]

Severe psoriatic arthritis

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
USTEKINUMAB **Initial 1, 2, 3, balance of supply**					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe	14916C	1	1	2	Steqeyma[a] *Ardelya*[a]
USTEKINUMAB **First continuing, balance of supply, subsequent continuing**					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe	14908P	1	1	1	Steqeyma[a] *Ardelya*[a]
USTEKINUMAB **Subsequent continuing**					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL syringe	14877B	1	1	1	Steqeyma[a] *Ardelya*[a]

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.