

5.29 USTEKINUMAB,

**Injection 45 mg in 0.5 mL single use pre-filled syringe,
Injection 90 mg in 1 mL single use pre-filled syringe,
Solution concentrate for I.V. infusion 130 mg in 26 mL
(5 mg per mL),**

Epyztek[®],

Samsung Bioepis AU PTY LTD.

1 Purpose of Submission

1.1 The Category 3 submission requested General Schedule and Section 100 (Highly Specialised Drugs Program) listings of a new biosimilar brand of ustekinumab (Epyztek[®]) in the following forms:

- 45 mg/0.5 mL pre-filled syringe (PFS)
- 90 mg/1 mL PFS
- 130 mg/26 mL injection vial

1.2 The submission requested listing on a cost-minimisation basis and under the same circumstances as the PBS-listed reference biologic Stelara[®], 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)

2 Background

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

Public Summary Document – March 2025 PBAC Meeting

Table 1: PBS-listed forms of ustekinumab versus requested dose forms

Indication	PBS listed dose forms (STELARA)	Recommended dosing (current PBS dose form units)	Requested dose forms (EPYZTEK)
Adult Severe CPP	45 mg vial	≤100 kg: 45 mg (1 x 45 mg vial) >100 kg: 90 mg (2 x 45 mg vial) SC injection at Weeks 0 and 4, then every 12 weeks	45 mg PFS
Paediatric severe CPP	45 mg vial	<60 kg: 0.75 mg/kg (portion of 45 mg vial) ≥60 to ≤100 kg: 45 mg (1 x 45 mg vial) >100 kg: 90 mg (2 x 45 mg vial) SC injection at Weeks 0 and 4, then every 12 weeks	45 mg PFS
Severe CD	45 mg vial 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 (2 x 45 mg vial)	45 mg PFS 130 mg vial
Severe PsA	45 mg vial	45 mg SC injection at Weeks 0 and 4, then every 12 weeks (1 x 45 mg vial)	45 mg PFS
MUSC	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 (1 x 90 mg PFS)	90 mg PFS 130 mg vial
Complex refractory fCD	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 (1 x 90 mg PFS)	90 mg PFS 130 mg vial

Source: Main submission body p.15

Abbreviations; CD = Crohn disease; CPP = chronic plaque psoriasis; fCD = fistulising Crohn disease; MUSC = moderate to severe ulcerative colitis; PFS = pre-filled syringe; PsA = Severe psoriatic arthritis; SC = subcutaneous

Registration status

2.2 Epyztek was TGA registered on 21 October 2024 as a biosimilar to Stelara and with the same indications.

3 Requested listing

3.1 The submission requested listing Epyztek under the same circumstances as Stelara, incorporating any amendments that were recommended by the PBAC at its March 2024 meeting (paragraph 6.1, ustekinumab (Stelara) Public Summary Document (PSD), March 2024 PBAC meeting).

3.2 The Secretariat noted that other biosimilar brands of ustekinumab were recommended by the PBAC in March 2024 (Wezlana®) and November 2024 (Steqeyma®) but are not yet listed. As per the biosimilar uptake driver policy, the restrictions for Epyztek should align with those for Wezlana and Steqeyma, which takes into account a lower level of authority.

3.3 At its March 2024 meeting, the PBAC advised that biosimilar uptake drivers, including the differential authority requirements for subsequent continuing treatment between the reference and biosimilar brand and inclusion of an administrative note encouraging the use of biosimilar brand for treatment naïve patients, should apply to Wezlana (paragraph 6.7, ustekinumab (Wezlana) PSD, March 2024 PBAC meeting).

Public Summary Document – March 2025 PBAC Meeting

3.4 At its November 2024 meeting, the PBAC advised that biosimilar uptake drivers should apply to Steqeyma, that is, to have an Authority Required (STREAMLINED) requirement for the subsequent continuing treatment listings and the inclusion of an administrative note across all Steqeyma listings encouraging use of the biosimilar brand for treatment naïve patients.

3.5 Shortened versions of the proposed listings reflecting the PBAC’s March and November 2024 recommendations for Wezlana and Steqeyma are presented below. Suggested additions are in italics and deletions are in strikethrough.

- Add Epyztek biosimilar listings, with schedule equivalence (‘a’ flag) for the same indications as Stelara.
- Amend Stelara listings as follows:
 - Add the Epyztek brand – Authority Required listing of Epyztek, with the Authority type for each treatment phase and indication to be consistent with current listings for Stelara. A separate Authority Required (STREAMLINED) listing of Epyztek for the subsequent continuing treatment restriction for relevant listings for Stelara.
 - Apply the ‘Biosimilar prescribing policy’ administrative note encouraging the use of biosimilar brands for treatment naïve patients:

Prescribing of the biosimilar brand Epyztek 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 biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the B Medicines webpage (www.health.gov.au/health-topics/medicines)

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	NEW	1	1	1	Epyztek
USTEKINUMAB First continuing whole body or face/hand/foot, balance of supply					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pre-filled syringe	NEW	1	1	1	Epyztek
USTEKINUMAB Subsequent continuing (whole body), subsequent continuing (face, hand, foot) – STREAMLINED					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pre-filled syringe	NEW	1	1	5	Epyztek
Indication: Severe chronic plaque psoriasis					
Prescribing Instructions: Two completed authority prescriptions should be submitted with every initial					

Public Summary Document – March 2025 PBAC Meeting

	application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats a total dose of 90 mg and no repeats.
	Prescribing Instructions: A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.

Severe chronic plaque psoriasis (paediatric)

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 (whole body or face, hand, foot)					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pre-filled syringe	NEW	1	1	2	Epyztek
First continuing (whole body), subsequent continuing (whole body), first continuing (face, hand, foot), subsequent continuing (face hand, foot)					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pre-filled syringe	NEW	1	1	1	Epyztek
Subsequent continuing (whole body), (face, hand, foot) – STREAMLINED					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pre-filled syringe	NEW	1	1	5	Epyztek
	Indication: Severe chronic plaque psoriasis				
	Prescribing Instructions: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats a total dose of 90 mg and no repeats.				
	Prescribing Instructions: A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.				

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					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pre-filled syringe	NEW	1	1	2	Epyztek
First continuing, balance of supply, subsequent continuing					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pre-filled syringe	NEW	1	1	1	Epyztek
Subsequent continuing - STREAMLINED					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pre-filled syringe	NEW	1	1	5	Epyztek

Public Summary Document – March 2025 PBAC Meeting

Severe Crohn disease

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
Initial 1, 2, 3, continuing treatment, balance of supply					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pre-filled syringe	NEW	2	2	0	Epyztek
Subsequent continuing – STREAMLINED					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pre-filled syringe	NEW	2	2	5	Epyztek
Initial 1, 2, 3					
ustekinumab 130 mg/26 mL injection, 26 mL vial	11164N (HS)	4	4	0	Stelara ^a Epyztek ^a
ustekinumab 130 mg/26 mL injection, 26 mL vial	11182M (HB)	4	4	0	Stelara ^a Epyztek ^a
Indication: Severe Crohn disease					
Prescribing Instructions: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats a total dose of 90 mg and no repeats.					
Prescribing Instructions: A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.					

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					
ustekinumab 130 mg/26 mL injection, 26 mL vial	13804M (HS)	4	4	0	Stelara ^a Epyztek ^a
ustekinumab 130 mg/26 mL injection, 26 mL vial	13781H (HB)	4	4	0	Stelara ^a Epyztek ^a
ustekinumab 90 mg/mL injection, 1 mL pre-filled syringe	13805N	1	1	0	Stelara ^a Epyztek ^a
Continuing treatment, transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements					
ustekinumab 90 mg/mL injection, 1 mL syringe	NEW	1	1	1	Epyztek
Subsequent continuing – STREAMLINED					
ustekinumab 90 mg/mL injection, 1 mL syringe	NEW	1	1	1	Epyztek
Indication: Complex refractory Fistulising Crohn disease					
Prescribing Instructions: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for 2 vials of 45 mg and no repeats a total dose of 90 mg and no repeats.					

Public Summary Document – March 2025 PBAC Meeting

	Prescribing Instructions: A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg (2 vials of 45 mg) with no repeats provide for an initial 16 week course of this drug will be authorised.
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Moderate to severe ulcerative colitis

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
Initial 1, 2, 3					
ustekinumab 130 mg/26 mL injection, 26 mL vial	13255P (HS)	4	4	0	Stelara ^a Epyztek ^a
ustekinumab 130 mg/26 mL injection, 26 mL vial	13272M (HB)	4	4	0	Stelara ^a Epyztek ^a
Initial 1, 2, 3					
ustekinumab 90 mg/mL injection, 1 mL syringe	13273N	1	1	0	Stelara ^a Epyztek ^a
First continuing, subsequent continuing, balance of supply					
ustekinumab 90 mg/mL injection, 1 mL syringe	13261Y	1	1	1	Stelara ^a Epyztek ^a
Subsequent continuing – STREAMLINED					
ustekinumab 90 mg/mL injection, 1 mL syringe	NEW	1	1	5	Epyztek

3.6 The submission noted that Stelara has a special pricing arrangement.

3.7 In accordance with Section 85C of the *National Health Act 1953*, medicines with the same drug, form and manner of administration are required to have the same approved ex-manufacturer price (AEMP).

4 Consideration of the evidence

Sponsor hearing

4.1 There was no hearing for this item.

Consumer comments

4.2 The PBAC noted and welcomed the input from the Australasian College of Dermatologists (ACD) via the Consumer Comments facility on the PBS website. ACD supported the PBS listing of Epyztek, particularly for the management of plaque psoriasis and psoriatic arthritis (in patients who are not responsive to other treatments), and considered that the availability of Epyztek may improve patient access to ustekinumab.

Clinical evidence

4.3 As per the Product Information, the TGA has confirmed that “Epyztek is a biosimilar medicine to Stelara (ustekinumab). The evidence for comparability supports the use of Epyztek for the listed indication.”

4.4 As a Category 3 submission, no evaluation of the clinical evidence was undertaken.

Estimated PBS usage and financial implications

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

5 PBAC Outcome

- 5.1 The PBAC recommended General Schedule and Section 100 (Highly Specialised Drugs Program) listings of a new biosimilar brand of ustekinumab (Epyztek[®]) in the following forms and under the same circumstances as the PBS-listed reference biologic, Stelara[®], for the same indications:

- Injection 45 mg in 0.5 mL in 0.5 mg pre-filled syringe (PFS)
- Injection 90 mg in 1 mL PFS
- Solution for I.V. infusion 130 mg in 26 mL

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

- 5.3 The PBAC advised the equi-effective doses to be the following:

- Epyztek 1 x 45 mg PFS = Stelara 1 x 45 mg PFS
- Epyztek 1 x 45 mg PFS = Stelara 1 x 45 mg injection vial
- Epyztek 1 x 90 mg PFS = Stelara 1 x 90 mg PFS
- Epyztek 1 x 90 mg PFS = Stelara 2 x 45 mg injection vial
- Epyztek 1 x 130 mg injection vial = Stelara 1 x 130 mg injection vial

- 5.4 The PBAC noted that the TGA has confirmed biosimilarity between Epyztek and the reference product Stelara.

- 5.5 The PBAC noted the biosimilar uptake driver policy, that is, an Authority Required (STREAMLINED) requirement for the subsequent continuing treatment listings and the inclusion of an administrative note across all Epyztek listings encouraging use of the biosimilar brand for treatment naïve patients. The PBAC considered that the application of biosimilar uptake drivers to Epyztek would be clinically appropriate and would not impact cost-effectiveness.

- 5.6 The PBAC advised that, under Section 101(4AACD) of the *National Health Act 1953*, in the Schedule of Pharmaceutical Benefits, the equivalent strengths and forms of Stelara PFS and Epyztek PFS should be treated as equivalent to each other for the purposes of substitution (i.e. 'a' flagged in the schedule); and likewise for the equivalent strengths and forms of Stelara and Epyztek injection vial. The PBAC noted that this means no 'a' flagging between vial and PFS.

- 5.7 The PBAC considered that the listing of Epyztek would not result in a net cost to the PBS as it would likely substitute for Stelara and not increase the overall market utilisation.
- 5.8 The PBAC noted its recommendation was on a cost-minimisation basis and advised that, because Epyztek 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.
- 5.9 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 items and indications requested for listing. As the submission requested the same restrictions as the reference brand, the full restrictions have not been reproduced. Shortened versions of new listings for Epyztek are presented below.
- 6.2 Add Epyztek biosimilar listings, with schedule equivalence ('a' flag) for the same indications as Stelara.
- 6.3 Amend Stelara listings as follows:
- Add the Epyztek brand – Authority Required listing of Epyztek, with the Authority type for each treatment phase and indication to be consistent with current listings for Stelara. A separate Authority Required (STREAMLINED) listing of Epyztek for the subsequent continuing treatment restriction for relevant listings for Stelara.
 - Apply the 'Biosimilar prescribing policy' administrative note encouraging the use of biosimilar brands for treatment naïve patients:

Prescribing of the biosimilar brand Epyztek 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 biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (www.health.gov.au/health-topics/medicines)

Public Summary Document – March 2025 PBAC Meeting

Severe chronic plaque psoriasis (adult)

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. 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	NEW	1	1	1	Epyztek
USTEKINUMAB First continuing whole body or face/hand/foot, balance of supply					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pre-filled syringe	NEW	1	1	1	Epyztek
USTEKINUMAB Subsequent continuing (whole body), subsequent continuing (face, hand, foot) – STREAMLINED					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pre-filled syringe	NEW	1	1	5	Epyztek
	Indication: Severe chronic plaque psoriasis				
	Prescribing Instructions: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for a total dose of 90 mg and no repeats.				
	Prescribing Instructions: A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg with no repeats provide for an initial 16 week course of this drug will be authorised.				

Severe chronic plaque psoriasis (paediatric)

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
Initial 1, 2, 3, balance of supply (whole body or face, hand, foot)					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pre-filled syringe	NEW	1	1	2	Epyztek
First continuing (whole body), subsequent continuing (whole body), first continuing (face, hand, foot), subsequent continuing (face hand, foot)					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pre-filled syringe	NEW	1	1	1	Epyztek
Subsequent continuing (whole body), (face, hand, foot) – STREAMLINED					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pre-filled syringe	NEW	1	1	5	Epyztek
	Indication: Severe chronic plaque psoriasis				
	Prescribing Instructions: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for a total dose of 90 mg and no repeats.				
	Prescribing Instructions: A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg with no repeats provide for an initial 16 week course of this drug will be authorised.				

Public Summary Document – March 2025 PBAC Meeting

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					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pre-filled syringe	NEW	1	1	2	Epyztek
First continuing, balance of supply, subsequent continuing					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pre-filled syringe	NEW	1	1	1	Epyztek
Subsequent continuing - STREAMLINED					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pre-filled syringe	NEW	1	1	5	Epyztek

Severe Crohn disease

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
Initial 1, 2, 3, continuing treatment, balance of supply					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pre-filled syringe	NEW	2	2	0	Epyztek
Subsequent continuing – STREAMLINED					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pre-filled syringe	NEW	2	2	5	Epyztek
Initial 1, 2, 3					
ustekinumab 130 mg/26 mL injection, 26 mL vial	11164N (HS)	4	4	0	Stelara ^a Epyztek ^a
ustekinumab 130 mg/26 mL injection, 26 mL vial	11182M (HB)	4	4	0	Stelara ^a Epyztek ^a
Indication: Severe Crohn disease					
Prescribing Instructions: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for a total dose of 90 mg and no repeats.					
Prescribing Instructions: A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg with no repeats provide for an initial 16 week course of this drug will be authorised.					

Public Summary Document – March 2025 PBAC Meeting

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					
ustekinumab 130 mg/26 mL injection, 26 mL vial	13804M (HS)	4	4	0	Stelara ^a Epyztek ^a
ustekinumab 130 mg/26 mL injection, 26 mL vial	13781H (HB)	4	4	0	Stelara ^a Epyztek ^a
ustekinumab 90 mg/mL injection, 1 mL pre-filled syringe	13805N	1	1	0	Stelara ^a Epyztek ^a
Continuing treatment, transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements					
ustekinumab 90 mg/mL injection, 1 mL syringe	NEW	1	1	1	Epyztek
Subsequent continuing – STREAMLINED					
ustekinumab 90 mg/mL injection, 1 mL syringe	NEW	1	1	1	Epyztek
Indication: Complex refractory Fistulising Crohn disease					
Prescribing Instructions: Two completed authority prescriptions should be submitted with every initial application for this drug. One prescription should be written under S100 (Highly Specialised Drugs) for a weight-based loading dose, containing a quantity of up to 4 vials of 130 mg and no repeats. The second prescription should be written under S85 (General) for a total dose of 90 mg and no repeats.					
Prescribing Instructions: A maximum quantity of a weight based loading dose is up to 4 vials with no repeats and the subsequent first dose of 90 mg with no repeats provide for an initial 16 week course of this drug will be authorised.					

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					
ustekinumab 130 mg/26 mL injection, 26 mL vial	13255P (HS)	4	4	0	Stelara ^a Epyztek ^a
ustekinumab 130 mg/26 mL injection, 26 mL vial	13272M (HB)	4	4	0	Stelara ^a Epyztek ^a
Initial 1, 2, 3					
ustekinumab 90 mg/mL injection, 1 mL syringe	13273N	1	1	0	Stelara ^a Epyztek ^a
First continuing, subsequent continuing, balance of supply					
ustekinumab 90 mg/mL injection, 1 mL syringe	13261Y	1	1	1	Stelara ^a Epyztek ^a
Subsequent continuing – STREAMLINED					
ustekinumab 90 mg/mL injection, 1 mL syringe	NEW	1	1	5	Epyztek

This restriction 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.