

5.23 USTEKINUMAB

**Injection 45 mg in 0.5 mL pre-filled syringe,
Injection 90 mg in 1 mL pre-filled syringe,
Solution for intravenous infusion 130 mg in 26 mL
vial,**

Steqeyma[®],

Celltrion Healthcare Australia Pty Ltd

1 Purpose of Submission

1.1 The Category 3 submission requested listing a new biosimilar brand of ustekinumab (UST) (Steqeyma[®]) 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[®] (and any new UST listings recommended by PBAC in March 2024) with the exception of the moderate to severe ulcerative colitis (MSUC) indication. The following indications were requested:

- Severe chronic plaque psoriasis (CPP)
- Severe psoriatic arthritis (PsA)
- Severe Crohn disease (CD)
- Complex refractory fistulising CD (fCD)

The pre-PBAC response requested listing for the MSUC indication.

2 Background

2.1 The following three formulations of UST are PBS-listed.

- UST 45 mg/0.5 mL injection vial is listed as an Authority Required listing for PsA, severe CD and severe CPP (adult and paediatric).
- UST 90 mg/1 mL PFS is listed as an Authority Required listing for MSUC and complex refractory fCD.
- UST 130 mg/26 mL injection vial is listed as Section 100 (Highly Specialised Drugs Program) Authority Required listing for severe CD, MSUC and complex refractory fCD.

2.2 Table 1 shows the current PBS-listed forms of UST and the submission’s requested dose forms.

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

Indication	PBS listed dose forms (Stelara)	Recommended dosing (current PBS dose form units)	Requested dose forms (Steqeyma)	Recommended dosing (requested dose form units)
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 90 mg PFS	≤100 kg: 45 mg (1 x 45 mg PFS) >100 kg: 90 mg (1 x 90 mg PFS) SC injection at Weeks 0 and 4, then every 12 weeks
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	≥60 to ≤100 kg: 45 mg (1 x 45 mg PFS) >100 kg: 90 mg (1 x 90 mg PFS) SC injection at Weeks 0 and 4, then every 12 weeks
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 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 or 12 weeks (1 x 90 mg PFS or 2 x 45 mg PFS)
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	45 mg SC injection at Weeks 0 and 4, then every 12 weeks (1 x 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)	N/A	N/A
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	Initiate with 260-520 mg IV infusion (2-4 x 130 mg vial) 90 mg SC injection at Week 8, then every 8 or 12 weeks (1 x 90 mg PFS)

Source: Main submission body p.8 and Steqeyma draft Product Information

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

2.3 Steqeyma was TGA registered on 11 September 2024 for the treatment of:

- 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 (60 kg and over) who are inadequately controlled by, or are intolerant to, other systemic therapies or phototherapies;
- alone or in combination with methotrexate, the 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;
- 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; and

- adult patients with moderately to severely active ulcerative colitis.

Previous PBAC consideration

- 2.4 Steqeyma has not been previously considered by the PBAC. Stelara is the only brand of UST currently listed on the PBS.
- 2.5 At its July 2023 meeting, the PBAC recommended the listing of UST for the treatment of fCD. UST for fCD was PBS-listed on 1 April 2024.
- 2.6 At its March 2024 meeting, the PBAC recommended the listing of a new biosimilar brand of UST, Wezlana, in 45 mg in 0.5 mL PFS, 45 mg in 0.5 mL vial, 90 mg in 0.5 mL PFS and 130 mg in 26 mL vial forms. The PBAC recommended listing Wezlana under the same circumstances as Stelara. The PBAC also recommended listing the 45 mg PFS for severe CPP (adult and paediatric) and PsA, and the 90 mg PFS for severe CD and adult CPP. Wezlana has not yet been PBS-listed.
- 2.7 At its March 2024 meeting, the PBAC also recommended the listing of Stelara 45 mg and 90 mg PFS and pre-filled pen (PFP) under the same circumstances as the currently listed UST 45 mg vial. Stelara 45 mg and 90 mg PFS and PFP have not yet been PBS-listed.

3 Requested listing

- 3.1 The submission requested listing Steqeyma under the same circumstances as the PBS-listed reference biologic Stelara and that the listings for Steqeyma are consistent with the biosimilar uptake driver policy.
- 3.2 The submission requested that Steqeyma be included in any UST listings recommended by the PBAC at its March 2024 meeting. This includes the recommendation to list a 90 mg PFS form of Wezlana, a biosimilar of UST, for severe CD and CPP.
- 3.3 The requested 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 Steqeyma are presented below.

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Listing of 45 mg/0.5 mL for severe CPP (paediatric)

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
USTEKINUMAB (Initial 1, 2, 3 whole body, or , face/hand/foot, balance of supply)					
ustekinumab 45 mg/0.5mL injection, 0.5 mL pre-filled syringe	NEW	1	1	2	Steqeyma
Restriction Summary [new] / Treatment of Concept: [new]					
	Category / Program: GENERAL – General Schedule				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)				
	Indication: Severe chronic plaque psoriasis				
	Administrative Advice: Biosimilar prescribing policy Prescribing of the biosimilar brand Steqeyma is encouraged for treatment naive patients. Prescribing of a biosimilar brand where available is encouraged for treatment naive patients				
	Administrative Advice: Encouraging biosimilar prescribing for treatment naive 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).				
	Administrative Advice: Pharmaceutical benefits that have the form ustekinumab 45 mg/0.5 mL, 0.5 mL vial and pharmaceutical benefits that have the form ustekinumab 45 mg/0.5 mL, 0.5 mL pre-filled syringes are equivalent for the purposes of substitution.				
	Prescribing Instructions: Where fewer than 5 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.				

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
USTEKINUMAB (First/Subsequent continuing treatment whole body, or, face/hand/foot)					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL vial	12664M	1	1	1	Stelara
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pre-filled syringe	NEW	1	1	1	Steqeyma
Restriction Summary [new] / Treatment of Concept: [new]					
	Category / Program: GENERAL – General Schedule				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (Streamlined)				
	Indication: Severe chronic plaque psoriasis				
	Administrative Advice: Biosimilar prescribing policy Prescribing of the biosimilar brand Steqeyma is encouraged for treatment naive patients.				
	Administrative Advice: Encouraging biosimilar prescribing for treatment naive 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).				
	Administrative Advice: Pharmaceutical benefits that have the form ustekinumab 45 mg/0.5 mL, 0.5 mL vial and pharmaceutical benefits that have the form ustekinumab 45 mg/0.5 mL, 0.5 mL pre-filled syringes are equivalent for the purposes of substitution.				

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MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
USTEKINUMAB (Subsequent continuing treatment whole body, or, face/hand/foot)					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pre-filled syringe	NEW	1	1	5	Steqeyma
Restriction Summary [new] / Treatment of Concept: [new]					
	Category / Program: GENERAL – General Schedule				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (Streamlined)				
	Indication: Severe chronic plaque psoriasis				
	Administrative Advice: Encouraging biosimilar prescribing for treatment naive 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).				
	Administrative Advice: Pharmaceutical benefits that have the form ustekinumab 45 mg/0.5 mL, 0.5 mL vial and pharmaceutical benefits that have the form ustekinumab 45 mg/0.5 mL, 0.5 mL pre-filled syringes are equivalent for the purposes of substitution.				

Listing of 45 mg/0.5 mL PFS for severe CPP (adult)

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
USTEKINUMAB (Initial 1,2,3 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	Steqeyma
Restriction Summary [new] / Treatment of Concept: [new]					
	Category / Program: GENERAL – General Schedule				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)				
	Indication: Severe chronic plaque psoriasis				
	Administrative Advice: Biosimilar prescribing policy Prescribing of the biosimilar brand Steqeyma is encouraged for treatment naive patients.				
	Administrative Advice: Encouraging biosimilar prescribing for treatment naive 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).				
	Administrative Advice: Pharmaceutical benefits that have the form ustekinumab 45 mg/0.5 mL, 0.5 mL vial and pharmaceutical benefits that have the form ustekinumab 45 mg/0.5 mL, 0.5 mL pre-filled syringes are equivalent for the purposes of substitution.				
	Prescribing Instructions: Where fewer than 5 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.				

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MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
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	Steqeyma
Restriction Summary [new] / Treatment of Concept: [new]					
	Category / Program: GENERAL – General Schedule				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)				
	Indication: Severe chronic plaque psoriasis				
	Administrative Advice: Biosimilar prescribing policy Prescribing of the biosimilar brand Steqeyma is encouraged for treatment naive patients.				
	Administrative Advice: Encouraging biosimilar prescribing for treatment naive 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).				
	Administrative Advice: Pharmaceutical benefits that have the form ustekinumab 45 mg/0.5 mL, 0.5 mL vial and pharmaceutical benefits that have the form ustekinumab 45 mg/0.5 mL, 0.5 mL pre-filled syringes are equivalent for the purposes of substitution.				
	Prescribing Instructions: Where fewer than 5 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.				

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
USTEKINUMAB (Subsequent continuing whole body, face, hand and foot)					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pre-filled syringe	NEW	1	1	5	Steqeyma
Restriction Summary [new] / Treatment of Concept: [new]					
	Category / Program: GENERAL – General Schedule				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)				
	Indication: Severe chronic plaque psoriasis				
	Administrative Advice: Encouraging biosimilar prescribing for treatment naive 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).				
	Administrative Advice: Pharmaceutical benefits that have the form ustekinumab 45 mg/0.5 mL, 0.5 mL vial and pharmaceutical benefits that have the form ustekinumab 45 mg/0.5 mL, 0.5 mL pre-filled syringes are equivalent for the purposes of substitution.				

Listing of 45 mg/0.5 mL PFS for PsA

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
USTEKINUMAB (Initial 1,2,3, balance of supply)					
ustekinumab 45 mg/0.5mL injection, 0.5 mL pre-filled syringe	NEW	1	1	2	Steqeyma

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Restriction Summary [new] / Treatment of Concept: [new]	
	Category / Program: GENERAL – General Schedule
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
	Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)
	Indication: Severe psoriatic arthritis
	Administrative Advice: Biosimilar prescribing policy Prescribing of the biosimilar brand Steqeyma is encouraged for treatment naive patients. Prescribing of a biosimilar brand where available is encouraged for treatment naive patients
	Administrative Advice: Encouraging biosimilar prescribing for treatment naive 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).
	Administrative Advice: Pharmaceutical benefits that have the form ustekinumab 45 mg/0.5 mL, 0.5 mL vial and pharmaceutical benefits that have the form ustekinumab 45 mg/0.5 mL, 0.5 mL pre-filled syringes are equivalent for the purposes of substitution.
	Prescribing Instructions: Where fewer than 5 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
USTEKINUMAB (Continuing treatment, balance of supply)					
ustekinumab 45 mg/0.5mL injection, 0.5 mL pre-filled syringe	NEW	1	1	1	Steqeyma

Restriction Summary [new] / Treatment of Concept: [new]	
	Category / Program: GENERAL – General Schedule
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
	Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)
	Indication: Severe psoriatic arthritis
	Administrative Advice: Encouraging biosimilar prescribing for treatment naive 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).
	Administrative Advice: Pharmaceutical benefits that have the form ustekinumab 45 mg/0.5 mL, 0.5 mL vial and pharmaceutical benefits that have the form ustekinumab 45 mg/0.5 mL, 0.5 mL pre-filled syringes are equivalent for the purposes of substitution.
	Prescribing Instructions: Where fewer than 5 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.

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Listing of 45 mg/0.5 mL for severe CD

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
USTEKINUMAB (Initial 1, 2, 3, continuing treatment, balance of supply)					
ustekinumab 45 mg/0.5mL injection, 0.5 mL pre-filled syringe	NEW	2	2	0	Steqeyma
Restriction Summary [new] / Treatment of Concept: [new]					
	Category / Program: GENERAL – General Schedule				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)				
	Indication: Severe Crohn disease				
	Administrative Advice: Biosimilar prescribing policy Prescribing of the biosimilar brand Steqeyma is encouraged for treatment naive patients. Prescribing of a biosimilar brand where available is encouraged for treatment naive patients				
	Administrative Advice: Encouraging biosimilar prescribing for treatment naive 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).				
	Administrative Advice: Pharmaceutical benefits that have the form ustekinumab 45 mg/0.5 mL, 0.5 mL vial and pharmaceutical benefits that have the form ustekinumab 45 mg/0.5 mL, 0.5 mL pre-filled syringes are equivalent for the purposes of substitution.				
	Prescribing Instructions: Where fewer than 5 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.				

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
USTEKINUMAB (continuing treatment)					
ustekinumab 45 mg/0.5mL injection, 0.5 mL pre-filled syringe	NEW	2	2	0	Steqeyma
Restriction Summary [new] / Treatment of Concept: [new]					
	Category / Program: GENERAL – General Schedule				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (Streamlined)				
	Indication: Severe Crohn disease				
	Administrative Advice: Encouraging biosimilar prescribing for treatment naive 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).				
	Administrative Advice: Pharmaceutical benefits that have the form ustekinumab 45 mg/0.5 mL, 0.5 mL vial and pharmaceutical benefits that have the form ustekinumab 45 mg/0.5 mL, 0.5 mL pre-filled syringes are equivalent for the purposes of substitution.				
	Prescribing Instructions: Where fewer than 5 vials in total are requested at the time of the application, authority approvals for a sufficient number of vials based on the patient's weight to complete dosing at weeks 0 and 8 may be requested by telephone through the balance of supply restriction.				

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Listing of 90 mg/1 mL PFS for severe CD (adult and paediatric)

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
USTEKINUAB (Initial 1,2,3, balance of supply)					
ustekinumab 90mg/mL injection, 1 mL pre-filled syringe	NEW	1	1	0	Steqeyma
Restriction Summary [new] / Treatment of Concept: [new]					
	Category / Program: GENERAL – General Schedule				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)				
	Indication: Severe Crohn disease				
	Administrative Advice: Biosimilar prescribing policy Prescribing of the biosimilar brand Steqeyma is encouraged for treatment naive patients. Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.				
	Administrative Advice: Encouraging biosimilar prescribing for treatment naive 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).				
	Administrative Advice: Pharmaceutical benefits that have the form ustekinumab 45 mg/0.5 mL, 0.5 mL vial and pharmaceutical benefits that have the form ustekinumab 45 mg/0.5 mL, 0.5 mL pre-filled syringes are equivalent for the purposes of substitution.				
	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.				

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
USTEKINUAB (continuing treatment,)					
ustekinumab 90mg/mL injection, 1 mL pre-filled syringe	NEW	1	1	0	Steqeyma
Restriction Summary [new] / Treatment of Concept: [new]					
	Category / Program: GENERAL – General Schedule				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (streamlined)				
	Indication: Severe Crohn disease				
	Administrative Advice: Encouraging biosimilar prescribing for treatment naive 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).				
	Administrative Advice: Pharmaceutical benefits that have the form ustekinumab 45 mg/0.5 mL, 0.5 mL vial and pharmaceutical benefits that have the form ustekinumab 45 mg/0.5 mL, 0.5 mL pre-filled syringes are equivalent for the purposes of substitution.				

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	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.

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
USTEKINUAB (continuing treatment)					
ustekinumab 90mg/mL injection, 1 mL pre-filled syringe	NEW	1	1	0	Steqeyma
Restriction Summary [new] / Treatment of Concept: [new]					
	Category / Program: GENERAL – General Schedule				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (Streamlined)				
	Indication: Severe Crohn disease				
	Administrative Advice: Biosimilar prescribing policy Prescribing of the biosimilar brand Steqeyma is encouraged for treatment naive patients. Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.				
	Administrative Advice: Encouraging biosimilar prescribing for treatment naive 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).				
	Administrative Advice: Pharmaceutical benefits that have the form ustekinumab 45 mg/0.5 mL, 0.5 mL vial and pharmaceutical benefits that have the form ustekinumab 45 mg/0.5 mL, 0.5 mL pre-filled syringes are equivalent for the purposes of substitution.				
	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.				
21164	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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Listing of 90 mg/1 mL PFS for severe CPP (adult and paediatric)

MEDICINAL PRODUCT Medicinal Product Pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
USTEKINUMAB (Initial 1,2,3 whole body, or, face/hand/foot, balance of supply paediatric CPP)					
ustekinumab injection 90 mg in 1 mL pre-filled syringe	NEW	1	1	2	Steqeyma
USTEKINUMAB (Initial 1,2,3 whole body, or, face/hand/foot, balance of supply adult CPP)					
ustekinumab injection 90 mg in 1 mL pre-filled syringe	NEW	1	1	2	Steqeyma
USTEKINUMAB (Continuing treatment whole body, or, face/hand/foot, grandfather treatment paediatric CPP)					
ustekinumab injection 90 mg in 1 mL pre-filled syringe	NEW	1	1	1	Steqeyma
USTEKINUMAB (Balance of supply continuing treatment whole body, or, face/hand/foot paediatric CPP)					
ustekinumab injection 90 mg in 1 mL pre-filled syringe	NEW	1	1	0	Steqeyma
USTEKINUMAB (Continuing treatment whole body, or face/hand/foot, balance of supply adult CPP)					
ustekinumab injection 90 mg in 1 mL pre-filled syringe	NEW	1	1	1	Steqeyma
Restriction Summary [new] / Treatment of Concept: [new]					
	Category / Program: GENERAL – General Schedule				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload), Authority Required (Streamlined)				
	Indication: Severe chronic plaque psoriasis				
	Administrative Advice: Biosimilar prescribing policy Prescribing of the biosimilar brand Steqeyma is encouraged for treatment naive patients. Prescribing of a biosimilar brand where available is encouraged for treatment naive patients				
	Administrative Advice: Encouraging biosimilar prescribing for treatment naive 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).				
	Administrative Advice: Pharmaceutical benefits that have the form ustekinumab 45 mg/0.5 mL, 0.5 mL vial and pharmaceutical benefits that have the form ustekinumab 45 mg/0.5 mL, 0.5 mL pre-filled syringes are equivalent for the purposes of substitution.				
	Treatment Phase: Initial treatment - Initial 1 (new patient) Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)				
	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.				

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Listing of 90 mg/1 mL PFS for severe fCD

MEDICINAL PRODUCT Medicinal Product Pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
USTEKINUMAB (Initial 1, 2, 3, balance of supply)					
USTEKINUMAB ustekinumab injection 90 mg in 1 mL pre-filled syringe	NEW	1	1	1	Steqeyma
USTEKINUMAB (Continuing treatment, transitioning from non-PBS to PBS-subsidised supply – Grandfather arrangements)					
ustekinumab injection 90 mg in 1 mL pre-filled syringe	NEW	1	1	0	Steqeyma
Restriction Summary [new] / Treatment of Concept: [new]					
	Category / Program: GENERAL – General Schedule				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload), Authority Required (Streamlined)				
	Indication: Complex refractory Fistulising Crohn disease				
	Administrative Advice: Biosimilar prescribing policy Prescribing of the biosimilar brand Steqeyma is encouraged for treatment naive patients. Prescribing of a biosimilar brand where available is encouraged for treatment naive patients				
	Administrative Advice: Encouraging biosimilar prescribing for treatment naive 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).				
	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.				

Listing of 130 mg/26 mL injection vial for severe CD

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
USTEKINUMAB (Initial 1, 2, 3)					
ustekinumab 130 mg/26 mL injection, 26 mL vial	11164N	4	4	0	Stelara Steqeyma
USTEKINUMAB (Initial 1, 2, 3)					
ustekinumab 130 mg/26 mL injection, 26 mL vial	11182M	4	4	0	Stelara Steqeyma
Restriction Summary [new] / Treatment of Concept: [new]					
	Category / Program: GENERAL – General Schedule				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload), Authority Required (Streamlined)				
	Indication: Severe Crohn disease				

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	<p>Administrative Advice: Biosimilar prescribing policy Prescribing of the biosimilar brand Steqeyma is encouraged for treatment naive patients. Prescribing of a biosimilar brand where available is encouraged for treatment naive patients.</p>
	<p>Administrative Advice: Encouraging biosimilar prescribing for treatment naive 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).</p>

Listing of 130 mg/26 mL injection vial for fCD

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
USTEKINUMAB (Initial 1, 2, balance of supply)					
ustekinumab 130 mg/26 mL injection, 26 mL vial	13804M (HS)	4	4	0	Stelara Steqeyma
USTEKINUMAB (Initial 1, 2, balance of supply)					
ustekinumab 130 mg/26 mL injection, 26 mL vial	13781H (HB)	4	4	0	Stelara Steqeyma
Restriction Summary [new] / Treatment of Concept: [new]					
	Category / Program: GENERAL – General Schedule				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)				
	Indication: Complex refractory Fistulising Crohn disease				
	<p>Administrative Advice: Biosimilar prescribing policy Prescribing of the biosimilar brand Steqeyma is encouraged for treatment naive patients. Prescribing of a biosimilar brand where available is encouraged for treatment naive patients</p>				
	<p>Administrative Advice: Encouraging biosimilar prescribing for treatment naive 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).</p>				
	<p>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.</p>				
	<p>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.</p>				

- 3.4 The submission requested that the authority level for all Steqeyma listings match those of Stelara, with the exception that the biosimilar uptake driver policy is applied to relevant listings for Steqeyma.

4 Comparator

- 4.1 The submission nominated Stelara as the main comparator. This was appropriate.

5 Consideration of the evidence

Sponsor hearing

5.1 There was no hearing for this item.

Consumer comments

5.2 The PBAC noted and welcomed the input from Crohn’s & Colitis Australia (CCA) via the Consumer Comments facility on the PBS website. CCA supported the listing of Steqeyma for the treatment of severe CD and complex refractory fCD noting that UST provides an important treatment option for people with CD who have not responded to other treatments. CCA considered that biosimilars of UST would provide an economic or access benefit to people living with inflammatory bowel disease and/or the community.

Clinical trials

5.3 The submission presented the following clinical trials to support the claim of the biosimilarity of Steqeyma to Stelara. These trials formed part of the TGA submission for Steqeyma.

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

Table 2: Studies presented in the submission.

Trial ID	Publication title	Publication citation
Study CT-P43 3.1	Clinical Study Report, 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. 2023. Papp KA, <i>et al.</i> 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.	NCT04673786 <i>BioDrugs</i> 2023; 38(1): 121-131.

Source: Main submission body p. 17

Comparative effectiveness

5.5 The primary endpoint of Study CT-P43 3.1 was mean change in psoriasis area and severity index (PASI) score at week 12 to demonstrate comparability in efficacy between Steqeyma and the reference product Stelara. At 12 weeks, the estimated treatment difference between the Steqeyma and Stelara groups was 0.94 (95% CI of -2.29, 4.16) which fell within the predefined equivalence margin of +/- 15% set by the sponsor. The TGA Delegate considered that these results supported the comparable efficacy between Steqeyma and Stelara for the indication of moderate to severe psoriasis and the biosimilarity between these two products (TGA Delegate’s Overview).

Comparative safety

- 5.6 The needle cover on the 90 mg PFS form of Stelara contains latex. The submission claimed that the latex-free formulation of Steqeyma provides a safety advantage given the consequences of allergic reactions to latex by patients, potential carers and health care providers.
- 5.7 The Product Information of Wezlana, which was cost-minimised to Stelara and recommended in March 2024, specifies that the vial and PFS forms are not made with natural rubber latex.
- 5.8 The TGA Delegate noted there did not appear to be any clear significant difference in the total frequency of treatment-emergent serious adverse events between Steqeyma and Stelara groups in Study CT-P43 3.1 (TGA Delegate's Overview). The ACM advised that there were no new or unexpected safety concerns for Steqeyma compared with Stelara (Steqeyma ACM minutes p. 6).

Clinical claim

- 5.9 The submission claimed that Steqeyma is non-inferior in terms of efficacy and superior in terms of safety compared to Stelara. The submission's claim of superior safety was made based on its latex-free formulation. PBAC considered that the claim of non-inferior comparative effectiveness was reasonable. The PBAC considered that the claim of superior safety was not adequately supported noting it was inconsistent with the TGA's conclusion that Steqeyma and Stelara are biosimilar, which indicates the products have similar efficacy and safety profiles.

Economic analysis

- 5.10 The submission presented a cost-minimisation analysis of Steqeyma compared with Stelara. The submission stated that Steqeyma will directly substitute on a mg-to-mg basis to Stelara.
- 5.11 The submission proposed that the price of the 45 mg PFS and 130 mg vial forms of Steqeyma be calculated on a cost-minimisation basis against the 45 mg and 130 mg vial forms of Stelara, respectively.
- 5.12 A premium of \$ [REDACTED] was originally sought by the sponsor for the 90 mg PFS form of Steqeyma. The requested premium was based on a cost-analysis which estimated a weighted average cost to the health care sector per patient with latex allergy necessitating hospitalisation. The sponsor withdrew the request for a premium following recategorisation of the submission to Category 3.
- 5.13 The submission used the published approved ex-manufacturer prices (AEMPs) for Stelara in the cost-minimisation analysis noting that Stelara has a Special Pricing Arrangement. The submission noted that if recommended, the price of Steqeyma will be adjusted to account for the statutory price reduction for the first new brand of UST listed on the PBS. The proposed indicative prices for Steqeyma are shown in Table 3.

5.14 As a Category 3 submission, the economic analysis has not been independently evaluated.

Table 3: Current published prices for Stelara and proposed indicative prices for Steqeyma

Stelara published prices			Steqeyma proposed prices	
Indication(s)	Form	AEMP	Form	AEMP
Severe CPP Severe PsA	45 mg vial	\$3,809.08	45 mg PFS	\$3,809.08
Severe CD	45 mg vial (max Qty=2)	\$7,618.16	45 mg PFS	\$3,809.08
			90 mg PFS	\$
Complex refractory fCD	90 mg PFS	\$3,809.08	90 mg PFS	
Severe CD Complex refractory fCD	130 mg vial	\$3,000.00	130 mg vial	\$3,000.00

Abbreviations; AEMP = approved ex-manufacturer price; CD = Crohn disease; CPP = chronic plaque psoriasis; fCD = fistulising Crohn disease; PFS = pre-filled syringe; PsA = Severe psoriatic arthritis

5.15 The proposed price for the 90 mg PFS form of Steqeyma was weighted by the 2023 PBS/RPBS UST scripts for severe CD (PBS item 11178H) and an estimate of the number of scripts for complex refractory fCD (PBS items 13805N, 13781H, 13804M and 13789R). A total of 36,995 scripts of Stelara 45 mg vial were dispensed under the severe CD indication in 2023. As UST was only listed for complex refractory fCD on 1 January 2024, the sponsor estimated 500 to < 5,000 scripts for this indication based on the assumption that complex refractory fCD represents 5% of severe CD (corresponding to % of scripts). For severe CD, the sponsor assumed that 50% of Stelara 45 mg vial usage would switch to the 90 mg (corresponding to % of scripts). Calculations for the weightings and the weighted price is shown below.

$$\text{Weighting}^{\text{severe CD}} = 50\% \times (36,955/36,955+500 \text{ to } < 5,000) = \%$$

$$\text{Weighting}^{\text{fCD}} = 500 \text{ to } < 5,000/36,955+500 \text{ to } < 5,000 = \%$$

$$\text{AEMP}^{90 \text{ mg}} = (\$3,809.08^{45 \text{ mg}} \times 2) \times \%^{\text{severe CD}} + \$3,809.08^{90 \text{ mg}} \times \%^{\text{fCD}} = \$$$

$$\% \times \%$$

Estimated PBS usage and financial implications

5.16 The submission adopted a market share approach to estimate the financial impact of listing Steqeyma. A summary of the assumptions is presented below.

Table 4: Summary of assumptions and inputs used in financial estimates.

Variable	Value	Assumption/source
Ustekinumab growth, annual	All services = 19%; by indication:	Estimated based on historical ustekinumab PBS services data (2019 – 2023)
Steqeyma uptake rates (%)	Yr 1 Yr 2 Yr 3 Yr 4 Yr 5 Yr 6	Estimated
Co-payment	PBS = \$23.99 RPBS = \$5.69	Calculated based on Stelara PBS utilisation for 2024

5.17 The submission stated that the listing of Steqeyma is anticipated to directly replace Stelara and, as such, not increase the overall use of UST.

5.18 Table 5 below shows the estimated number of scripts, cost of Steqeyma to the PBS/RPBS, and the net financial implications to the PBS/RPBS. The pre-PBAC response included revised financial estimates which excludes the price premium previously sought and incorporates listing for the MSUC indication. The table reflects the revised financial estimates. The financial impact to Services Australia will be determined by that agency as part of the post-PBAC process.

Table 5: Estimated use and financial implications

Year	2025	2026	2027	2028	2029	2030
Number of scripts (PBS/RPBS)	█ ¹	█ ²	█ ³	█ ³	█ ⁴	█ ⁴
Cost to PBS	█ ⁵	█ ⁶	█ ⁷	█ ⁷	█ ⁷	█ ⁷
Less co-payments	█ ⁸	█ ⁸	█ ⁸	█ ⁸	█ ⁸	█ ⁸
Net cost to PBS	█ ⁵	█ ⁶	█ ⁷	█ ⁷	█ ⁷	█ ⁷
Cost to RPBS	█ ⁹	█ ⁹	█ ⁹	█ ⁹	█ ⁹	█ ⁹
Less co-payments	█ ⁸	█ ⁸	█ ⁸	█ ⁸	█ ⁸	█ ⁸
Net cost to RPBS	█ ⁹	█ ⁹	█ ⁹	█ ⁹	█ ⁹	█ ⁹
Total cost to PBS/RPBS	█ ⁵	█ ⁶	█ ⁷	█ ⁷	█ ⁷	█ ⁷
Net cost of displaced Stelara to PBS/RPBS	█ ⁸	█ ⁸	█ ⁸	█ ⁸	█ ⁸	█ ⁸
Net cost to PBS/RPBS	█ ⁹	█ ⁹	█ ⁹	█ ⁹	█ ⁹	█ ⁹

Abbreviations: PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme.

Source: pp. 94-96 of the submission

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 \$20 million to < \$30 million

6 \$50 million to < \$60 million

7 \$100 million to < \$200 million

8 net cost saving

9 \$0 to < \$10 million

5.19 The pre-PBAC response noted that the financial estimates may be misleading given published prices are used. The pre-PBAC response indicated that listing Steqeyma is expected to be at least cost neutral to Government.

6 PBAC Outcome

6.1 The PBAC recommended the listing of a new biosimilar brand of ustekinumab (UST) (Steqeyma) in the following forms and under the same circumstances as the PBS-listed reference biologic, Stelara, for the treatment of adult and paediatric severe chronic

plaque psoriasis (CPP), severe Crohn disease (CD), moderate to severe ulcerative colitis (UC), complex refractory fistulising CD and severe psoriatic arthritis (PsA):

- 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

- 6.2 The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of Steqeyma would be acceptable if it were cost-minimised to Stelara at the effective price.
- 6.3 The PBAC advised the equi-effective doses to be the following:
- Steqeyma 1 x 45 mg PFS = Stelara 1 x 45 mg PFS
 - Steqeyma 1 x 45 mg PFS = Stelara 1 x 45 mg injection vial
 - Steqeyma 1 x 90 mg PFS = Stelara 1 x 90 mg PFS
 - Steqeyma 1 x 90 mg PFS = Stelara 2 x 45 mg injection vial
 - Steqeyma 1 x 130 mg injection vial = Stelara 1 x 130 mg injection vial
- 6.4 The PBAC noted the TGA Delegate's view that based on the submitted pharmacokinetic, clinical and quality data, Steqeyma is comparable to Stelara and that biosimilarity between these products has been demonstrated.
- 6.5 The PBAC noted the TGA Delegate considered the extrapolation of indications for Steqeyma to all the indications of Stelara in Australia appropriate. The PBAC considered the claim of non-inferior comparative effectiveness was appropriate and consistent with the TGA's assessment. The PBAC considered that the claim of superior safety was not adequately supported given the TGA's conclusion of biosimilarity between Steqeyma and Stelara.
- 6.6 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.
- 6.7 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 Steqeyma 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 Steqeyma injection vial.
- 6.8 The PBAC considered that the listing of Steqeyma would not result in a net cost to the PBS as it would likely substitute Stelara and not increase the overall market utilisation.

- 6.9 The PBAC noted its recommendation was on a cost-minimisation basis and advised that, because Steqeyma 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.
- 6.10 The PBAC noted this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

- 7.1 Add Steqeyma biosimilar listings, with schedule equivalence ('a' flag) for the same indications as Stelara.
- 7.2 Amend Stelara listings as follows:

- Add the Steqeyma brand
- Apply the 'Biosimilar prescribing policy' administrative note encouraging the use of biosimilar brands for treatment naïve patients:

Prescribing of the biosimilar brand Steqeyma 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)

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	Steqeyma
ustekinumab 90 mg/mL injection, 1 mL pre-filled syringe	NEW	1	1	2	Steqeyma
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	Steqeyma
ustekinumab 90 mg/mL injection, 1 mL pre-filled syringe	NEW	1	1	1	Steqeyma
USTEKINUMAB Subsequent continuing (whole body), subsequent continuing (face, hand, foot) – STREAMLINED					

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ustekinumab 45 mg/0.5 mL injection, 0.5 mL pre-filled syringe	NEW	1	1	5	Steqeyma
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 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	Steqeyma
ustekinumab 90 mg/mL injection, 1 mL pre-filled syringe	NEW	1	1	2	Steqeyma
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	12664M	1	1	1	Stelara ^a Steqeyma ^a
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pre-filled syringe	NEW	1	1	1	Steqeyma
ustekinumab 90 mg/mL injection, 1 mL pre-filled syringe	NEW	1	1	1	Steqeyma
Balance of supply, continuing treatment (whole body or face/hand/foot)					
ustekinumab 90 mg/mL injection, 1 mL pre-filled syringe	NEW	1	1	0	Steqeyma
Continuing treatment whole body, or, face/hand/foot, grandfather treatment					
ustekinumab 90 mg/mL injection, 1 mL pre-filled syringe	NEW	1	1	1	Steqeyma
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	Steqeyma
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.					

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Severe psoriatic arthritis

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

Severe Crohn disease

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. 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	Steqeyma
ustekinumab 90 mg/mL injection, 1 mL pre-filled syringe	NEW	1	1	0	Steqeyma
Subsequent continuing – STREAMLINED					
ustekinumab 45 mg/0.5 mL injection, 0.5 mL pre-filled syringe	NEW	2	2	5	Steqeyma
Initial 1, 2, 3					
ustekinumab 130 mg/26 mL injection, 26 mL vial	11164N (HS)	4	4	0	Stelara ^a Steqeyma ^a
ustekinumab 130 mg/26 mL injection, 26 mL vial	11182M (HB)	4	4	0	Stelara ^a Steqeyma ^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.				

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Complex refractory fistulising Crohn disease

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. 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 Steqeyma ^a
ustekinumab 130 mg/26 mL injection, 26 mL vial	13781H (HB)	4	4	0	Stelara ^a Steqeyma ^a
ustekinumab 90 mg/mL injection, 1 mL pre-filled syringe	13805N	1	1	0	Stelara ^a Steqeyma ^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	Steqeyma
Subsequent continuing – STREAMLINED					
ustekinumab 90 mg/mL injection, 1 mL syringe	NEW	1	1	1	Steqeyma
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.					
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.					

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

This restriction 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.