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5.12 ADALIMUMAB, Injection 20 mg in 0.2 mL pre-filled syringe, Yuflyma®, Celltrion Australia Pty Ltd

1 Purpose of Submission

1.1 The Category 4 submission requested to list adalimumab injection 20 mg in 0.2 mL pre-filled syringe (Yuflyma®; hereafter referred to as 'Yuflyma') under the same circumstances as the PBS-listed adalimumab injection 20 mg in 0.2 mL pre-filled syringe (Humira®; hereafter referred to as 'Humira').

1.2 Listing was requested on the basis of a cost-minimisation basis versus Humira.

2 Background

Registration status

2.1 Yuflyma was TGA registered on 21 August 2025 and determined to be biosimilar to the reference brand Humira.

Previous PBAC consideration

2.2 Humira, the reference brand and innovator, was the first brand of adalimumab listed on the PBS on 1 May 2004 for the treatment of severely active rheumatoid arthritis in adults, following a recommendation for listing by the PBAC at its December 2003 meeting.

2.3 The PBAC recommended adalimumab biosimilar brand, Amgevita 20 mg in 0.4 mL pre-filled syringe (PFS) at its July 2018 meeting.

2.4 The PBAC recommended adalimumab biosimilar brand, Yuflyma 40 mg in 0.4 mL PFS and pre-filled pen (PFP) at its July 2022 meeting.

2.5 The PBAC recommended Yuflyma 80 mg in 0.8 mL PFS and PFP at its March 2024 meeting.

- Yuflyma PFP should not be considered equivalent for the purposes of substitution with any adalimumab PFS, consistent with its previous considerations of adalimumab (Paragraphs 6.1-6.5, Yuflyma, Public Summary Document [PSD], July 2022).

2.6 At its December 2024 meeting, the PBAC recommended Humira for the treatment of enthesitis/spondylitis related juvenile idiopathic arthritis (ERA). The PBAC advised this recommendation should also apply to the adalimumab biosimilars that are TGA -registered for these indications. This indication was PBS listed on 1 January 2026.

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Current status

2.7 Humira PFS and adalimumab (Amgevita) injection 20 mg in 0.4 mL PFS are currently listed on the PBS as an Authority Required (Telephone/Online) and Authority Required (STREAMLINED) listing for:

- moderate to severe ulcerative colitis,
- severe active juvenile idiopathic arthritis,
- severe Crohn disease,
- vision threatening non-infectious uveitis,
- severe chronic plaque psoriasis, and
- enthesitis/spondylitis related juvenile idiopathic arthritis.

2.8 Humira, the reference biologic, and adalimumab biosimilar brands in forms other than 20 mg in 0.2 mL PFS, Amgevita, Hadlima, Hyrimoz, Abrilada and Yuflyma, are currently listed on the PBS.

3 Requested listing

3.1 The submission requested listing Yuflyma under the same circumstances as the PBS-listed reference biologic Humira.

3.2 The requested restrictions are complex due to the number of items and indications required for the listing. If recommended by the PBAC, the implementation of these listings may occur across separate stages. As the submission requested the same restrictions as the reference brand, the full restrictions have not been reproduced here. An example of the requested listing is provided below:

Name, restriction, manner of administration, form	Max. Qty (packs)	Max. Qty (units)	No. of repeats	PBS item code	Proprietary name
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2ml syringes	1	2	3	12371D	[a]Humira® [a]Yuflyma®
Category / Program: ☒ GENERAL - General Schedule (Code GE)					
Prescriber type: ☒ Medical Practitioners					
Restriction type: ☒ Authority Required (written only via post/HPOS upload)					
Indication: Moderate to severe ulcerative colitis					
Treatment Phase: Initial treatment - Initial 1 (new patient)					

3.3 The submission requested a different authority type of Authority Required (Streamlined) be applied to the listing of Yuflyma for the following indications and treatment phases:

- moderate to severe ulcerative colitis for treatment phases in
    - first continuing
    - continuing
    - balance of supply
- severe chronic plaque psoriasis for treatment phases in
    - continuing treatment
- severe Crohn disease for treatment phases in
    - first continuing
    - balance of supply
- vision threatening non-infectious uveitis for treatment phases in
    - continuing
    - balance of supply.

3.4 Noting that an adalimumab biosimilar brand with the same strength but different form, Amgevita 20 mg in 0.4 mL PFS, is already PBS listed, the PBAC was requested to advise if it is more appropriate to align the authority types of Yuflyma with that of Amgevita listings in the requested indications. It is noted that Amgevita listings have the same authority types as Humira in the requested indications with the exception of the continuing treatment of vision threatening non-infectious uveitis - Amgevita is listed as Authority Required (STREAMLINED), consistent with biosimilar uptake policy.

3.5 The submission requested Yuflyma to have Authority Required (STREAMLINED) for the continuing treatment of vision threatening non-infectious uveitis. The Secretariat noted that Amgevita is already listed with this authority type and it is appropriate to also apply for Yuflyma.

3.6 The submission did not include a request for the newly listed indication, ERA as it was listed on 1 January 2026. The PBAC is asked to advise if Yuflyma should also be listed for the ERA indication if recommended for listing.

3.7 The PBAC was asked to advise under section 101(4AACD) of the *National Health Act 1953* ("the Act") whether the Minister should be advised that the Yuflyma 20 mg PFS, Humira 20 mg PFS and Amgevita 20 mg PFS brands of adalimumab could be marked as equivalent in the Schedule of Pharmaceutical Benefits for the purposes of substitution (i.e., 'a'-flagged in the Schedule).

3.8 The PBAC was asked to advise whether biosimilar uptake drivers, including the differential authority requirements for subsequent continuing treatment between the reference and biosimilar brands; and inclusion of an administrative note encouraging the use of biosimilar brands for treatment naïve patients, should apply to Yuflyma pre-filled syringe if it is recommended for listing.

3.9 Table 1 summarises the requested changes.

Table 1: Summary of the requesting listing changes.

Restriction	Treatment phase	PBS Listing	Item No.	Current restriction level	Restriction level requested	Max Qty packs	Max Qty units	No. of repeats	Item code affected ('a' flagged to Amgevita):
Moderate to severe ulcerative colitis	Initial Treatments	General Schedule	12371D	AR Written (initial 1, 2, 3) AR tel/elec (initial BOS)	No change requested	1	2	3	12350B
	First continuing; Continuing-Balance of supply	General Schedule	12337H	AR tel/elec (1st cont and cont. BOS)	Change to Streamlined (Bio-similar Uptake Drivers)	1	2	5	12357J
	Subsequent Continuing Treatment	General Schedule	14996G	AR Streamlined	No change requested	1	2	5	12351C
Severe active juvenile idiopathic arthritis (Paed)	Initial Treatments	HSD Public	12406Y	AR tel/elec	No change requested	1	2	0	12435L
	Initial Treatments	HSD Private	12443X	AR tel/elec	No change requested	1	2	0	12439Q
	Continuing Treatment	HSD Private	13292N	AR Streamlined	No change requested	1	2	5	12349Y
	Continuing Treatment	HSD Public	13293P	AR Streamlined	No change requested	1	2	5	12417M
Severe chronic plaque psoriasis (Paed)	Initial Treatments	General Schedule	14976F	AR Written (initial 1, 2, 3) AR tel/elec (initial BOS)	No change requested	1	2	4	14975E
	First continuing	General Schedule	14997H	AR Written	Change to Streamlined (Bio-similar Uptake Drivers)	1	2	5	14998J
	Subsequent continuing Treatment	General Schedule	15039M	AR Streamlined	No change requested	1	2	5	15005R
Severe Crohn disease (Paed)	Initial Treatments	General Schedule	12407B	AR Written (initial 1, 2, 3)	No change requested	1	2	3	12332C
	Balance of Supply	General Schedule	12423W	AR tel/elec (BOS)	Change to Streamlined (Bio-similar Uptake Drivers)	1	2	0	12354F
	First continuing	General Schedule	12424X	AR Written	Change to Streamlined	1	2	5	12440R

Restriction	Treatment phase	PBS Listing	Item No.	Current restriction level	Restriction level requested	Max Qty packs	Max Qty units	No. of repeats	Item code affected ('a' flagged to Amgevita):
					(Bio-similar Uptake Drivers)				
	Subsequent continuing Treatment	General Schedule	14995F	AR Streamlined	No change requested	1	2	5	12436M
Vision threatening non-infectious uveitis	Initial Treatments	General Schedule	14244Q	AR Written	No change requested	1	2	6	14748F
	Balance of Supply	General Schedule	14245R	AR tel/elec (BOS)	Change to Streamlined (Bio-similar Uptake Drivers)	1	2	0	14749G
	Continuing Treatment	General Schedule	14275H	AR tel/elec	Change to Streamlined (Bio-similar Uptake Drivers)	1	2	5	14747E 14772L (ST)
Enthesitis/ spondylitis related juvenile idiopathic arthritis	Initial and initial BOS	General Schedule	15148G	AR tel/elec	Not Requested	1	2	3	15155P
	Grandfather	General Schedule	15190L	AR tel/elec	Not Requested	1	2	5	15172M
	Continuing	General Schedule	15149H	AR Streamlined	Not Requested	1	2	5	15180Y

AR= Authority Required, BOS= Balance of Supply, tel/elec= Telephone/Electronic, Paed= Paediatrics, ST= (STREAMLINED) authority

4 Comparator

4.1 The submission nominated the reference brand of adalimumab, Humira, as the main comparator. This is considered appropriate because Humira was previously accepted by PBAC as a comparator to Yuflyma (July 2022 and March 2024), and to other adalimumab biosimilar brands of adalimumab.

4.2 The submission suggested the adalimumab biosimilar brand, Amgevita 20 mg in 0.4 mL injection and syringe is not a primary comparator as it contains twice the volume of liquid and is less convenient for injecting. This is not considered appropriate and should be a relevant comparator as the PBAC recommended listing of Amgevita as a biosimilar to Humira 20 mg in 0.2 mL (Amgevita PSD, July 2018) and Amgevita 20 mg in 0.4 mL PFS is currently listed on the PBS.

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5 Consideration of the evidence

Sponsor hearing

5.1 There was no hearing for this item.

Consumer inputs

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

Clinical evidence

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

5.4 The submission stated that no new clinical trial data or other comparative data was presented as the clinical trial data would be the same as its previous submission for 40 mg Yuflyma (paragraph 5.5. Yuflyma, PSD, July 2022). The submission sought listing of an additional strength of Yuflyma (20 mg/0.2 mL) to those already listed on the PBS (Yuflyma 40 mg in 0.4 mL and 80 mg in 0.8 mL PFS and PFP).

Clinical claim

5.5 The submission claimed non-inferior comparative effectiveness and non-inferior comparative safety for Yuflyma compared with Humira.

5.6 The submission claimed that 'On a mg for mg basis the adalimumab in Yuflyma is therapeutically equivalent to the adalimumab (prefilled syringe) of any other brand in terms of both clinical efficacy and safety.' The approved Product Information stated *Yuflyma is biosimilar to Humira.*

Economic analysis

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

5.8 The submission presented a cost-minimisation approach of Yuflyma compared with Humira. The equi-effective doses presented in the submission were 1 mg of adalimumab in Yuflyma 20 mg in 0.2 mL = 1 mg of adalimumab in Yuflyma 40 mg in 0.4 mL = 1 mg of adalimumab 20 mg in 0.2 mL (any other brand). It is also noted that the Yuflyma equi-effective doses should be considered with relevant comparator Amgevita 20 mg. Therefore 1 mg of adalimumab in Yuflyma 20 mg in 0.2 mL = 1 mg of adalimumab in Yuflyma 40 mg in 0.4 mL = 1 mg of adalimumab 20 mg in 0.2 mL (any brand) = 1 mg of adalimumab in Amgevita 20 mg in 0.4 mL.

5.9 The submission requested the same AEMP for injection Yuflyma as injection Humira for the equivalent form and strength.

Estimated PBS usage and financial implications

5.10 The submission stated that it is expected that Yuflyma will substitute for Humira over the next six years and would not expect to grow the market. The submission used the PBS

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services volumes from calendar year 2026. It assumes Yuflyma will displace [redacted]% of Humira scripts in 2026, [redacted]% in 2027, and continuing at [redacted]% from 2028.

5.11 The submission estimated a nil net financial impact to the PBS/RPBS over a period of six years.

Table 2: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use						
Number of scripts dispensed	[redacted][1]	[redacted][1]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]
Estimated financial implications of Yuflyma						
Cost to PBS/RPBS less co-payment	$0	$0	$0	$0	$0	$0
Net financial implications						
Net cost to PBS/RPBS	$0	$0	$0	$0	$0	$0

Abbreviations: PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme.
Source: Submission's financial model spreadsheet.
The redacted figures correspond to the following ranges:
[1] *< 500*
[2] *500 to < 5,000*

6 PBAC Outcome

6.1 The PBAC recommended the Authority Required listing of adalimumab (Yuflyma) in the form of 20 mg in 0.2 mL pre-filled syringe (PFS) under the same circumstances as the PBS--listed reference biologic Humira 20 mg in 0.2 mL PFS and more specifically, the biosimilar brand Amgevita 20 mg in 0.4mL PFS for the following indications and treatment phases:

- moderate to severe ulcerative colitis for treatment phases in
  - first continuing
  - continuing
  - balance of supply
- severe chronic plaque psoriasis for treatment phases in
  - continuing treatment
- severe Crohn disease for treatment phases in
  - first continuing
  - balance of supply
- vision threatening non-infectious uveitis for treatment phases in
  - continuing
  - balance of supply

- enthesitis/spondylitis related juvenile idiopathic arthritis
    - continuing.

6.2 The PBAC's recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness of Yuflyma 20 mg in 0.2 mL PFS would be acceptable if it were cost-minimised to Humira.

6.3 The PBAC advised the equi-effective doses to be 1 mg of Yuflyma = 1 mg of Humira.

6.4 The PBAC noted and accepted Yuflyma 20 mg in 0.2 mL PFS has been determined to be biosimilar to the reference brand Humira.

6.5 The PBAC recalled its advice from its December 2025 Intracycle meeting that Humira was recommended for the treatment of enthesitis/spondylitis related juvenile idiopathic arthritis (ERA). The PBAC advised this recommendation should also apply to the Yuflyma as it is TGA-registered for these indications.

6.6 The PBAC considered that the nominated comparator of Humira was appropriate. The PBAC considered that Amgevita 20 mg in 0.4 mL, which is another biosimilar to Humira was also an appropriate comparator.

6.7 The PBAC advised that it is more appropriate to align the authority types of Yuflyma with that of Amgevita listings in the requested indications, noting it is a biosimilar brand of Humira. The PBAC noted that Amgevita listings are consistent with biosimilar uptake policy.

6.8 The PBAC advised that biosimilar uptake drivers, including the differential authority requirements for subsequent continuing treatment between the reference and biosimilar brands and inclusion of an administrative note encouraging the use of biosimilar brands for treatment naïve patients, should apply to Yuflyma 20 mg in 0.2 mg PFS.

6.9 The PBAC noted the non-inferior comparative effectiveness and non-inferior comparative safety for Yuflyma compared with Humira, and that on a mg for mg basis the adalimumab in Yuflyma is therapeutically equivalent to the adalimumab (PFS) of any other brand in terms of both clinical efficacy and safety.

6.10 The PBAC advised that, under section 101(4AACD) of the Act, in the Schedule of Pharmaceutical Benefits, Yuflyma PFS should not be considered equivalent for the purposes of substitution with any adalimumab PFP, consistent with its previous considerations of adalimumab. Noting that currently all adalimumab 20 mg injections are listed as PFS.

6.11 The PBAC advised that, under section 101(4AACD) of the Act, in the Schedule of Pharmaceutical Benefits that Yuflyma 20 mg in 0.2 mL PFS, Humira 20 mg in 0.2 mL PFS and Amgevita 20 mg in 0.4 mL PFS should be treated as equivalent to each other for the purposes of substitution (i.e. 'a' flagged in the schedule).

6.12 The PBAC considered that the listing of Yuflyma 20 mg in 0.2 mL PFS is expected to be cost-neutral to Government given that Yuflyma will likely substitute for the reference biologic Humira and therefore not increase overall market utilisation.

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

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

Outcome:
Recommended

7 Recommended listing

Add new adalimumab brand (Yuflyma 20 mg in 0.2 mL pre-filled syringe (PFS)) with schedule equivalence ('a' flag) for the same indications as Humira and Amgevita 20 mg in 0.4mL with the Authority type for each treatment phase and indication to be consistent with current listings for Amgevita 20 mg in 0.4 mL PFS as follows:

Add Yuflyma® 20mg/0.2ml brand to the below indications and item codes:

Moderate to severe ulcerative colitis:

Name, restriction, manner of administration, form	PBS item Code	Max. Qty (packs)	Max. Qty (units)	No. of repeats	Proprietary name
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2ml syringes	12371D	1	2	3	[a]Humira® [a]*Yuflyma*®
Category / Program: ☒ GENERAL - General Schedule (Code GE)					
Prescriber type: ☒ Medical Practitioners					
Restriction type: ☒ Authority Required (written only via post/HPOS upload)					

Indication: Moderate to severe ulcerative colitis
Treatment Phase: Initial treatment - Initial 1 (new patient)
Indication: Moderate to severe ulcerative colitis
Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)
Indication: Moderate to severe ulcerative colitis
Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)
Restriction type: ☒ Authority Required (telephone/online PBS Authorities system)
Indication: Moderate to severe ulcerative colitis
Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years) - balance of supply

Name, restriction, manner of administration, form	PBS item Code	Max. Qty (packs)	Max. Qty (units)	No. of repeats	Proprietary name
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2ml syringes	12337H	1	2	5	[a]Humira® [a]*Yuflyma*®
Category / Program: ☒ GENERAL - General Schedule (Code GE)					
Prescriber type: ☒ Medical Practitioners					
Restriction type: ☒ Authority Required (telephone/online PBS Authorities system)					
Indication: Moderate to severe ulcerative colitis					
Treatment Phase: First continuing treatment					
Indication: Moderate to severe ulcerative colitis					
Treatment Phase: Continuing treatment - balance of supply					

Name, restriction, manner of administration, form	PBS item code	Max. Qty (packs)	Max. Qty (units)	No. of repeats	Proprietary name
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2ml syringes	14996G	1	2	5	[a]Humira® [a]*Yuflyma*®
Category / Program: ☒ GENERAL - General Schedule (Code GE)					
Prescriber type: ☒ Medical Practitioners					
Restriction type: ☒ Authority Required (STREAMLINED)					
Indication: Moderate to severe ulcerative colitis					
Treatment Phase: Subsequent continuing treatment					

Severe active juvenile idiopathic arthritis- under 18 years of age

Name, restriction, manner of administration, form	PBS item code	Max. Qty (packs)	Max. Qty (units)	No. of repeats	Proprietary name
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2ml syringes	12406Y (Public) 12443X (Private)	1	2	0	[a]Humira® [a]*Yuflyma*®
Category / Program: ☒ Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)					
Prescriber type: ☒ Medical Practitioners					
Restriction type: ☒ Authority Required (telephone/online PBS Authorities system)					
Indication: Severe active juvenile idiopathic arthritis					
Treatment Phase: Initial treatment - Initial 1 (new patient)					
Indication: Severe active juvenile idiopathic arthritis					
Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months)					
Indication: Severe active juvenile idiopathic arthritis					
Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months)					
Indication: Severe active juvenile idiopathic arthritis					
Treatment Phase: Initial 1 (new patient) or Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 12 months) or Initial 3 (recommencement of treatment after a break in biological medicine of more than 12 months) - balance of supply					

Name, restriction, manner of administration, form	PBS item code	Max. Qty (packs)	Max. Qty (units)	No. of repeats	Proprietary name
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2ml syringes	13293P (Public) 13292N (Private)	1	2	5	[a]Humira® [a]*Yuflyma*®
Category / Program: ☒ Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)					
Prescriber type: ☒ Medical Practitioners					
Restriction type: ☒ Authority Required (Streamlined)					
Indication: Severe active juvenile idiopathic arthritis					
Treatment Phase: Continuing treatment					

Name, restriction, manner of administration, form	PBS item code	Max. Qty (packs)	Max. Qty (units)	No. of repeats	Proprietary name
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2ml syringes	15156Q (Public) 15173N (Private)	1	2	5	[a]Humira® [a]*Yuflyma*®
Category / Program: ☒ Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)					
Prescriber type: ☒ Medical Practitioners					
Restriction type: ☒ Authority Required (telephone/online PBS Authorities system)					
Indication: Severe active juvenile idiopathic arthritis					
Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements					

Severe chronic plaque psoriasis- under 18 years of age

Name, restriction, manner of administration, form	PBS item code	Max. Qty (packs)	Max. Qty (units)	No. of repeats	Proprietary name
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2ml syringes	14976F	1	2	4	[a]Humira® [a]*Yuflyma*®
Concept ID (for internal Dept. use)	**Category / Program:** ☒ GENERAL - General Schedule (Code GE)				
	Prescriber type: ☒ Medical Practitioners				
	Restriction type: ☒ Authority Required (in writing only via post/HPOS upload)				
Indication: Severe chronic plaque psoriasis					
Treatment Phase: Initial 1 treatment (Whole body) - biological medicine-naive patient					
Indication: Severe chronic plaque psoriasis					
Treatment Phase: Initial 2 treatment (Whole body) - Change of treatment, or, recommencement of treatment after a break in biological medicine of less than 5 years					
Indication: Severe chronic plaque psoriasis					
Treatment Phase: Initial 3 treatment (Whole body, or, face/hand/foot) - Recommencement of treatment after a break in biological medicine of more than 5 years					
Restriction type: ☒ Authority Required (telephone/online PBS Authorities system)					
Indication: Severe chronic plaque psoriasis					
Treatment Phase: Balance of supply - Initial 1, 2 or 3 treatment (Whole body, or, face/hand/foot)					
Indication: Severe chronic plaque psoriasis					
Treatment Phase: Initial 1 treatment (Face, hand, foot) - biological medicine-naive patient					
Indication: Severe chronic plaque psoriasis					
Treatment Phase: Initial 2 treatment (Face, hand, foot) - Change of treatment, or, recommencement of treatment after a break in biological medicine of less than 5 years					

Name, restriction, manner of administration, form	PBS item code	Max. Qty (packs)	Max. Qty (units)	No. of repeats	Proprietary name
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2ml syringes	14997H	1	2	5	[a]Humira® [a]*Yuflyma*®
Category / Program: ☒ GENERAL - General Schedule (Code GE)					
Prescriber type: ☒ Medical Practitioners					
Restriction type: ☒ Authority Required (in writing only via post/HPOS upload)					
Indication: Severe chronic plaque psoriasis					
Treatment Phase: First continuing treatment, Whole body					
Indication: Severe chronic plaque psoriasis					
Treatment Phase: First continuing treatment, Face, hand, foot					

Name, restriction, manner of administration, form	PBS item code	Max. Qty (packs)	Max. Qty (units)	No. of repeats	Proprietary name
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2ml syringes	15039M	1	2	5	[a]Humira® [a]*Yuflyma*®
Category / Program: ☒ GENERAL - General Schedule (Code GE)					
Prescriber type: ☒ Medical Practitioners					
Restriction type: ☒ Authority Required (Streamlined)					
Indication: Severe chronic plaque psoriasis					
Treatment Phase: Subsequent continuing treatment, Whole body					
Indication: Severe chronic plaque psoriasis					
Treatment Phase: Subsequent continuing treatment, Face, hand, foot					

Severe Crohn disease - paediatric patient:

Name, restriction, manner of administration, form	PBS item code	Max. Qty (packs)	Max. Qty (units)	No. of repeats	Proprietary name
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2ml syringes	12407B	1	2	3	[a]Humira® [a]*Yuflyma*®
Category / Program: ☒ GENERAL - General Schedule (Code GE)					
Prescriber type: ☒ Medical Practitioners					
Restriction type: ☒ Authority Required (in writing only via post/HPOS upload)					
Indication: Severe Crohn disease					
Treatment Phase: Initial treatment - Initial 1 (new patient)					
Indication: Severe Crohn disease					
Treatment Phase: Initial treatment - Initial 2 (change or recommencement of treatment after a break in biological medicine of less than 5 years)					
Indication: Severe Crohn disease					
Treatment Phase: Initial treatment - Initial 3 (recommencement of treatment after a break in biological medicine of more than 5 years)					

Name, restriction, manner of administration, form	PBS item code	Max. Qty (packs)	Max. Qty (units)	No. of repeats	Proprietary name
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2ml syringes	12424X	1	2	5	[a]Humira® [a]*Yuflyma*®
Category / Program: ☒ GENERAL - General Schedule (Code GE)					
Prescriber type: ☒ Medical Practitioners					
Restriction type: ☒ Authority Required (in writing only via post/HPOS upload)					
Indication: Severe Crohn disease					
Treatment Phase: First continuing treatment of Crohn disease in a paediatric patient					

Name, restriction, manner of administration, form	PBS item code	Max. Qty (packs)	Max. Qty (units)	No. of repeats	Proprietary name
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2ml syringes	14995F	1	2	5	[a]Humira® [a]*Yuflyma*®
Category / Program: ☒ GENERAL - General Schedule (Code GE)					
Prescriber type: ☒ Medical Practitioners					
Restriction type: ☒ Authority Required (Streamlined)					

Indication: Severe Crohn disease
Treatment Phase: Subsequent continuing treatment of Crohn disease in a paediatric patient

Name, restriction, manner of administration, form	PBS item code	Max. Qty (packs)	Max. Qty (units)	No. of repeats	Proprietary name
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2ml syringes	12423W	1	2	0	[a]Humira® [a]*Yuflyma*®
Category / Program: ☒ GENERAL - General Schedule (Code GE)					
Prescriber type: ☒ Medical Practitioners					
Restriction type: ☒ Authority Required (telephone/online PBS Authorities system)					
Indication: Severe Crohn disease					
Treatment Phase: Balance of supply for paediatric patient					

Vision threatening non-infectious uveitis:

Name, restriction, manner of administration, form	PBS item code	Max. Qty (packs)	Max. Qty (units)	No. of repeats	Proprietary name
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2ml syringes	14244Q	1	2	6	[a]Humira® [a]*Yuflyma*®
Category / Program: ☒ GENERAL - General Schedule (Code GE)					
Prescriber type: ☒ Medical Practitioners					
Restriction type: ☒ Authority Required (in writing only via post/HPOS upload)					
Indication: Vision threatening non-infectious uveitis					
Treatment Phase: Initial treatment					
Indication: Vision threatening non-infectious uveitis					
Treatment Phase: Recommencement of treatment					

Name, restriction, manner of administration, form	PBS item code	Max. Qty (packs)	Max. Qty (units)	No. of repeats	Proprietary name
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2ml syringes	14245R	1	2	0	[a]Humira® [a]*Yuflyma*®
Category / Program: ☒ GENERAL - General Schedule (Code GE)					
Prescriber type: ☒ Medical Practitioners					
Restriction type: ☒ Authority Required (telephone/online PBS Authorities system)					
Indication: Vision threatening non-infectious uveitis					

Treatment Phase: Balance of Supply

Name, restriction, manner of administration, form	**PBS item code**	**Max. Qty (packs)**	**Max. Qty (units)**	**No. of repeats**	**Proprietary name**
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2ml syringes	14275H	1	2	5	[a]Humira® [a]*Yuflyma*®
Category / Program: ☒ GENERAL - General Schedule (Code GE)					
Prescriber type: ☒ Medical Practitioners					
Restriction type: ☒ Authority Required (telephone/online PBS Authorities system)					
Indication: Vision threatening non-infectious uveitis					
Treatment Phase: Continuing treatment					

Enthesitis/spondylitis related juvenile idiopathic arthritis

Name, restriction, manner of administration, form	**PBS item code**	**Max. Qty (packs)**	**Max. Qty (units)**	**No. of repeats**	**Proprietary name**
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2ml syringes	15148G	1	2	3	[a]*Yuflyma*®
Category / Program: ☒ GENERAL - General Schedule (Code GE)					
Prescriber type: ☒ Medical Practitioners					
Restriction type: ☒ Authority Required (telephone/online PBS Authorities system)					
Indication: Enthesitis/spondylitis related juvenile idiopathic arthritis					
Treatment Phase: Initial treatment					
Indication: Enthesitis/spondylitis related juvenile idiopathic arthritis					
Treatment Phase: Initial treatment - balance of supply					

Name, restriction, manner of administration, form	**PBS item code**	**Max. Qty (packs)**	**Max. Qty (units)**	**No. of repeats**	**Proprietary name**
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2ml syringes	15149H	1	2	5	[a]*Yuflyma*®
Category / Program: ☒ GENERAL - General Schedule (Code GE)					
Prescriber type: ☒ Medical Practitioners					
Restriction type: ☒ Authority Required (Streamlined)					
Indication: Enthesitis/spondylitis related juvenile idiopathic arthritis					

Treatment Phase: Continuing treatment

Name, restriction, manner of administration, form	PBS item code	Max. Qty (packs)	Max. Qty (units)	No. of repeats	Proprietary name
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2ml syringes	15190L	1	2	5	[a]*Yuflyma*®
Category / Program: ☒ GENERAL - General Schedule (Code GE)					
Prescriber type: ☒ Medical Practitioners					
Restriction type: ☒ Authority Required (telephone/online PBS Authorities system)					
Indication: Enthesitis/spondylitis related juvenile idiopathic arthritis					
Treatment Phase: Transitioning from non-PBS to PBS-subsidised treatment - Grandfather arrangements					

Create new Authority Required (STREAMLINED), Subsequent continuing treatment listing for Yuflyma for Vision threatening non-infectious uveitis in line with Amgevita listing, item code: 14772L

Name, restriction, manner of administration, form	PBS item code	Max. Qty (packs)	Max. Qty (units)	No. of repeats	Proprietary name
ADALIMUMAB					
adalimumab 20 mg/0.2 mL injection, 2 x 0.2ml syringes	NEW (SAME AS 14772L)	1	2	5	[a]Humira® [a]*Yuflyma*®
Category / Program: ☒ GENERAL - General Schedule (Code GE)					
Prescriber type: ☒ Medical Practitioners					
Restriction type: ☒ Authority Required (STREAMLINED)					
Indication: Vision threatening non-infectious uveitis					
Treatment Phase: Continuing treatment					

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.